





October 28, 2021 FY2021 Q2 EARNINGS ANNOUNCEMENT

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# **AGENDA**

O1. Introduction Christophe Weber President & CEO
O2. R&D Engine Andy Plump President, R&D
O3. Financial Strength Costa Saroukos Chief Financial Officer
O4. Q&A Session

# **CONVICTION IN OUR STRATEGY: ACCELERATING TOPLINE & PIPELINE**



### Acceleration of topline growth driven by 14 Global Brands

- H1 underlying revenue growth +6.8%¹; reported revenue growth +12.8%
- 14 Global Brands underlying revenue growth +11.4% with further acceleration expected in H2; now represent 42% of total core revenue
- Operational excellence and innovation across PDT value chain to meet supply commitments; plasma donations consistently surpassing pre-pandemic levels
- Confirming full-year FY2021 guidance of "mid-single digit" underlying revenue growth and underlying Core Operating Profit growth<sup>2</sup>

### Committed to grow revenue through an innovative pipeline

- Continuing to invest in highly innovative pipeline of approx. 40 clinical stage assets, with multiple POC milestones expected in H2
- EXKIVITY approval in the U.S. as first new launch from Wave 1 pipeline; Maribavir unanimously recommended by FDA Advisory Committee<sup>3</sup> (PDUFA Nov 23rd)
- Pevonedistat did not meet primary endpoint in HR-MDS; TAK-994 studies stopped due to safety signal with next steps being assessed
- Collaboration with JCR Pharmaceuticals in Hunter syndrome, and planned acquisition of GammaDelta Therapeutics to further strengthen cell therapy capabilities
- Topline growth momentum expected to continue driven by 14 Global Brands, new product launches, and COVID-19 vaccines
- Share buyback of up to JPY 100B underscores confidence in business strategy & commitment to delivering value to our shareholders
  - Hikari Warning Letter Update: On October 13, 2021, the U.S. Food and Drug Administration (FDA) revised the inspection classification of the Hikari manufacturing site to Voluntary Action Indicated (VAI). The FDA determined that the conditions in the Warning Letter dated June 2020 have been addressed and the Warning Letter is now closed.
  - 1. Please refer to slide 34 for definition and slides 46 & 48 for reconciliation
  - 2. Please refer to slide 28 for FY2021 forecast and guidance
  - 3. Recommended use of maribavir for the treatment of refractory cytomegalovirus (CMV) infection and disease, with or without genotypic resistance to ganciclovir, valganciclovir, foscarnet or cidofovir in transplant recipients PDT: Plasma-Derived Therapies; POC: Proof of Concept

# PROGRESS WITH VACCINE PARTNERSHIPS TO COMBAT COVID-19



Vaccine	Mechanism	Current status
Novavax' COVID-19	Recombinant s-protein vaccine candidate against SARS-CoV-2 adjuvanted with Matrix-M	<ul> <li>Partnership with Novavax in Japan for the development, manufacturing (250 million doses/year and commercialization of their COVID-19 vaccine candidate for the pandemic and beyond at our Hikari facility in Japan</li> </ul>
Vaccine Candidate, TAK-019		<ul> <li>Agreement with Government of Japan's Ministry of Health, Labour and Welfare (MHLW) for the purchase of 150 million doses of TAK-019</li> </ul>
(in-license from Novavax)		<ul> <li>Takeda aims to distribute the first doses in Japan in early calendar year 2022, subject to regulatory approval</li> </ul>
COVID-19 Vaccine Moderna	mRNA vaccine against SARS-CoV-2	<ul> <li>Three-way agreement with Moderna and the Government of Japan's MHLW to import and distribute 100 million doses of Moderna's COVID-19 vaccine in Japan</li> </ul>
Intramuscular		50 million doses have been delivered to Japan
<b>Injection</b> (in-license from Moderna)		<ul> <li>Takeda plans to start to import and distribute an additional 50 million doses as early as the beginning of 2022</li> </ul>

- FY2021 guidance only includes the contribution from the first 50 million doses of the Moderna vaccine
- Pricing of TAK-019 in Japan will be determined in agreement with Japan's MHLW and will take into consideration financial support provided by the Japanese government to establish manufacturing capacity and conduct appropriate clinical trials in Japan
- Pricing of COVID-19 Vaccine Moderna Intramuscular Injection in Japan is determined in agreement with MHLW and Moderna



## FIRST AND ONLY APPROVED ORAL THERAPY TO TARGET EGFR EXON20 INSERTION+ NSCLC



### **NSCLC Exon20 Insertion Mutation** Market



 EGFR Exon20 insertion mutations are diagnosed in ~2K Non-Small Cell Lung Cancer (NSCLC) patients/year in the U.S.



- Until recently, there have not been any effective, targeted treatment options for these patients
  - 2L patients (unspecified mutation) treated with docetaxel after platinumbased chemo achieve a median Progression Free Survival of 3-4 months & Overall Response Rate ~15%



 Polymerase chain reaction (PCR) testing identifies <50% of all EGFR Exon20 insertion mutations; Next-generation sequencing (NGS) testing is able to detect all EGFR Exon20 variants

### **EXKIVITY Profile**



- FDA granted accelerated approval in Sept 2021 for the treatment of mNSCLC with EGFR Exon20 insertion mutations after platinum-based chemotherapy
- NGS companion diagnostic test approved simultaneously to support identification of patients with EGFR Exon20 insertion mutations



- Demonstrated efficacy:
  - Objective response rate (per IRC): 28%
  - Duration of response: 17.5 mo
  - Progression free survival: 7.3 mo
  - Median overall survival: 24 mo



Safety consistent with EGFR TKI class\*



Oral dosing

### **Launch Execution**



• First patient treated within one week of U.S. launch



• Lung portfolio synergies with ALUNBRIG



- Pivotal data from EXCLAIM published by JAMA
- Ongoing Ph3 trial in 1L, EXKIVITY monotherapy vs Chemo



- EMA Submission June 2021
- China Submission accepted July 2021; Breakthrough designation
  - · Additional filings as part of **Project ORBIS**

# **AGENDA**

04.

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 O3. Financial Strength Costa Saroukos Chief Financial Officer

**Q&A Session** 

## **UPDATES TO OUR PIPELINE SINCE Q1 ANNOUNCEMENT**



# PROGRAM

### **WAVE 1 PIPELINE**

- EXKIVITY (mobocertinib): Approved by FDA, first oral specifically designed for EGFR Exon20+ NSCLC
- Maribavir: FDA Advisory Committee unanimously recommends use for post-transplant recipients with CMV¹ infection and disease refractory to treatment with or without resistance.
- Pevonedistat: PANTHER trial did not meet primary endpoint in HR MDS<sup>2</sup>
- TAK-994: Ph2 trials stopped as a precautionary measure due to a liver safety signal.
   Unblinding trial will allow for assessment of the benefit/risk profile in NT1 and development timelines.

### **GLOBAL AND REGIONAL BRANDS**

- ENTYVIO SC: Feedback from the FDA has provided clarity on the regulatory package and critical elements for the BLA submission. We are reviewing our development program timelines and currently anticipate potential approval in FY2023.
- VYVANSE: Pediatric written request in the US was completed and approved by FDA, providing 6 months additional market exclusivity. We now expect loss of exclusivity in the U.S. to occur in late August 2023.
- Approval of ALOFISEL in Japan<sup>3</sup>
- Label expansions approved for CABOMETYX in Japan and VOCINTI in China<sup>4</sup>

### **BUSINESS DEVELOPMENT**

- Collaboration and license agreement to commercialize JR-141 (pabinafusp alfa), a next-generation Hunter Syndrome Therapy designed to deliver proteins to the brain and peripheral tissues.
- Announced intent to acquire GammaDelta Therapeutics to accelerate the development of allogeneic gamma delta T-cell therapies; scheduled to close Q1 FY22, contingent on completion of antitrust reviews<sup>5</sup>.
- Takeda entered into three next generation gene therapy collaborations:
- 1) Selecta Biosciences, 2) Poseida Therapeutics, and 3) Immusoft

- CMV = cytomegalovirus
- Pevonedistat: no regulatory path forward in HR MDS or AML
- 3. ALOFISEL approved in Japan for the treatment of complex perianal fistulas in patients with non-active or mildly active luminal Crohn's disease
- I. CABOMETYX received an additional approval in Japan for the treatment of unresectable or metastatic renal cell carcinoma in combination with nivolumab; VOCINTI received an additional approval for the maintenance treatment of reflux esophagitis in China
- . Acquisition follows a multi-year collaboration between Takeda and GammaDelta Therapeutics formed in 2017 to develop the novel γδ T cell therapy platforms, in which Takeda received an equity stake and an exclusive right to purchase GammaDelta.

# **OUR PIPELINE IS STARTING TO DELIVER VALUE**



WAVE 1<sup>1</sup> WAVE 2<sup>2</sup> **CLINICAL-STAGE NMEs** 

POTENTIAL APPROVAL	FY21	FY22	FY23	FY24	FY25 and Bey	/ond			
<del>j</del>	EXKIVITY <sup>3</sup> 2L NSCLC with EGFR exon 20 insertion mutation		EXKIVITY <sup>3</sup> 1L NSCLC with EGFR exon 20 insertion mutation	TAK-007 CD19+ hematologic malignancies	subasumstat <sup>3</sup> Multiple cancers	TAK-676 Solid tumors	TAK-252 Solid tumors	TAK-102 Multiple cancers	
ONCOLOGY					modakafusp alfa³ R/R MM	<b>TAK-605</b> Multiple cancers	TAK-186 EGFR Solid Tumor	<b>TAK-940</b> CD19+ hematologic malignancies	
RARE GENETICS &	maribavir R/R CMV infect. in transplant	<b>TAK-609</b> Hunter CNS (IT) <sup>4</sup>	maribavir 1L CMV infect. in HSCT	<b>TAK-611</b> MLD (IT)	<b>TAK-755</b> <i>iTTP, SCD</i>	mezagitamab MG, ITP	TAK-607  Complications of prematurity		
HEMATOLOGY			<b>TAK-755</b> cTTP  ● 🏕	• • •	pabinafusp alfa <sup>6</sup>     Hunter Syndrome	• • *			
			soticlestat  DS  •	orexin 2R-ag TAK-9947 NT1	orexin 2R-ag TAK-861 NT1, NT2, IH, Other ● ● 🎺	orexin 2R-ag TAK-994 <sup>7</sup> NT2, IH, Other	TAK-653 <sup>8</sup> Inadequate resp. in MDD	<b>TAK-341</b> Parkinson's Disease	
NEUROSCIENCE			soticlestat LGS		orexin 2R-ag TAK-925 Hospital setting, NT1	<b>TAK-071</b> Parkinson's Disease	<b>TAK-041</b> <sup>8</sup> Anhedonia in MDD		
	<b>● ∲ Eohilia</b> <sup>5</sup> FoE Approval date TBD				TAK-999  AATD Liver Disease	TAK-062 Celiac Disease	TAK-101 Celiac Disease	sibofimloc Crohn's Disease (post-op and ileitis)	TAK-510 Nausea & vomiting
GASTRO- ENTEROLOGY	Approval date 16D				<b>TAK-906</b> Gastroparesis	TAK-954 POGD	<b>TAK-951</b> Nausea & vomiting	TAK-039 Hepatic encephalopathy	TAK-105 Nausea & vomiting
rejt.	<b>TAK-019</b> Novavax COVID-19 Vaccine (JP)	<b>TAK-003</b> Dengue Vaccine			TAK-426 Zika Vaccine				
VACCINES	COVID-19 Vaccine Moderna Intramuscular Injection (JP)		U.S. Breakthrough and/or Fast Track Designations	<ul> <li>China Breakthrouş</li> <li>Japan SAKIGAKE D</li> </ul>		n potential in at least	one indication	APPROVED [	New addition

- Potential approval dates depend on data read-outs; some WAVE 1 target approval dates assume accelerated approval Certain WAVE 2 programs may be accelerated into WAVE 1 depending on future data read outs
- EXKIVITY (brand) mobocertinib (generic); subasumstat (generic) TAK-981; modakafusp alfa (generic) TAK-573
- Filing of TAK-609 is subject to feedback from regulatory agencies on the ongoing extension trial and may change
- In active discussions with the FDA. Potential approval subject to outcome of discussions.

- 6. Pabinafusp alfa (generic) JR-141, partnership with JCR Pharmaceuticals
- 7. TAK-994 approval timelines under review
- 8. Partnership with Neurocrine Biosciences

Takeda's Fiscal Year ends March 31 of the following year; e.g., "FY21" refers to the twelve-month period ending March 31, 2022. All timelines are approximate estimates of October 28, 2021. For glossary of disease abbreviations please refer to appendix.

# **UPDATE ON ORAL OREXIN AGONIST TAK-994**



### TAK-994 has shown transformative efficacy in NT1 patients (with >30 min MWT)

 FDA and Chinese regulatory authority granted Breakthrough Therapy Designations and EMA granted PRIME Designation for NT1

### Safety Signal for TAK-994 in Ph2

- A liver safety signal emerged in the Ph2 1501 part B (8 week) study and its extension study 1504
- There was a single patient who had a significant liver function test (LFT) elevation (reported as a serious adverse event)
- In addition, there was an increased frequency of protocol defined discontinuations due to increased LFTs across the two studies

## Ph2 study and long-term extension terminated to fully evaluate benefit/risk

- Terminating studies allows Takeda to unblind the full data set
- Full assessment to be presented at a future medical conference

**Determine future path for TAK-994 program – FY22** 

# TAKEDA'S LEADERSHIP POSITION IN THE OREXIN AGONIST FIELD



### Pioneering the Orexin Field with a Multi-Asset Franchise of Clinical and Pre-clinical Programs

### TAK-861, Long-acting oral orexin agonist

- Distinct profile to TAK-994
- Fast Track designation granted by FDA July 2021 for NT1
- Ph1 started in healthy volunteer subjects in April 2021
- Ph1b healthy volunteer and narcolepsy early efficacy and safety data FY22

### TAK-925, Short-acting IV formulation

- Demonstrated strong efficacy and proof-of-concept in NT1, NT2, IH and OSA with >30 min MWT
- Safety data available in more than 200 subjects across HV, NT1, NT2, IH and OSA patients for up to one week
- Ph1 started in anesthetized adults Q3 FY21; data expected H1 FY22

### Continue to invest in new orexin agonist molecules with distinct profiles

- Takeda is deeply committed to patients that might benefit from this novel MOA
- Apply extensive preclinical, clinical and regulatory knowledge acquired to multiple assets

# MARIBAVIR: REDEFINING POST-TRANSPLANT CMV TREATMENT



## Oral viral protein kinase inhibitor for CMV



# Disease Background

- CMV is the most common post-transplant viral infection (>25% of transplants)<sup>1</sup>
- CMV infection may result in higher rates of transplant failure (2–6x risk) and mortality (2.6x risk)<sup>2</sup>

# Regulatory Updates and Milestones

- In October, the FDA advisory committee unanimously recommended maribavir for patients post-transplant with refractory CMV infection with or without resistance
- FDA PDUFA date November 23rd
- Potential EU approval in H1 FY22
- 1L CMV post HSCT trial on track and expected to read out H1 FY22
- 1L CMV post HSCT US filing expected mid-FY22

# Maribavir Ph3 SOLSTICE trial in R/R CMV demonstrated:

- Superior efficacy (>2x IAT<sup>4</sup>)
- Favorable tolerability and safety profile
- 10x less toxicity (neutropenia/acute kidney injury)
- Oral administration

Efficacy and Safety <sup>3</sup>	maribavir N=235	IAT <sup>4</sup> N=117
Primary: Viremia clearance	55.7% p-value	23.9%
Neutropenia	1.7%	(V)GCV:25.0%
Acute kidney injury	1.7%	FOS: 19.1%
Taste disturbance	44.0%	1.7%

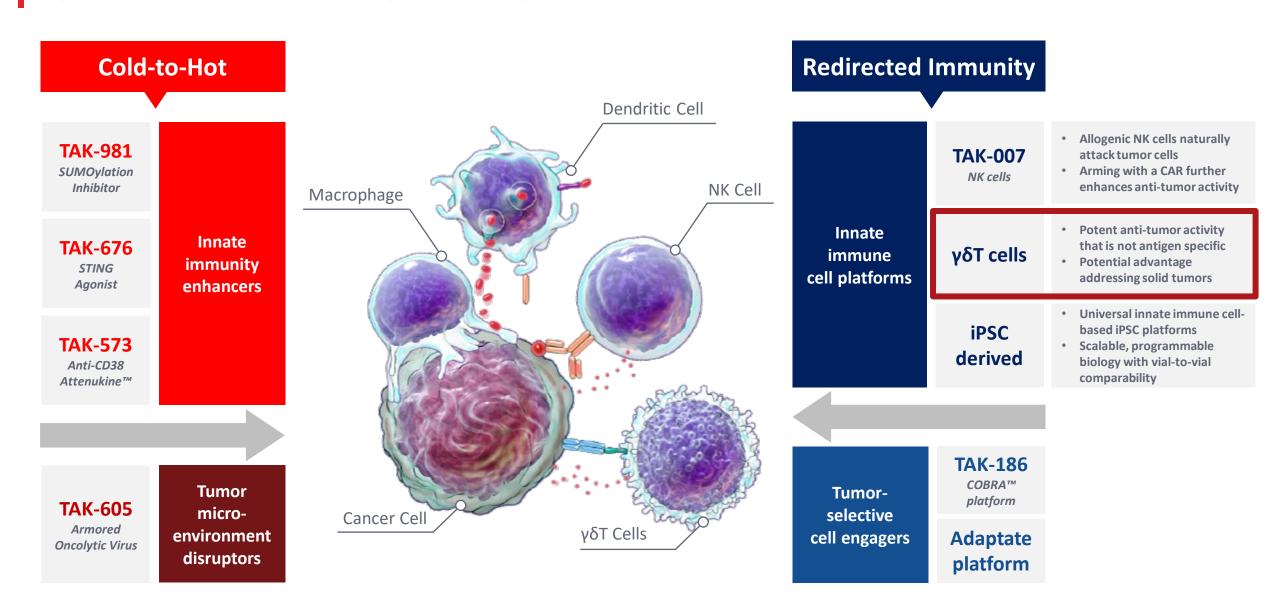
<sup>1.</sup> Stern et al. Front Microbiol. 2019 May28;10:1186. Ramanan et al. Solid Organ Transplantation: A Review. InfectChemother. 2013 Sep; 45(3): 260–27

<sup>2.</sup> Stern et al. Transplantation. 2014 Nov 15;98(9):1013-8. Jorgenson et al. Transpl Infect Dis . 2019 Jun;21(3):e13080

<sup>3.</sup> Duarte et al. Presentation EBMT 2021

# GAMMADELTA EXPANDS ABILITY TO TARGET SOLID TUMORS WITH OUR CELL THERAPY PORTFOLIO





# **OUR PIPELINE CONTINUES TO ADVANCE**



	MOA	TAU /BU	EXPECTED EVENT <sup>1</sup>	FY21		COMMENTS
Eohilia TAK-721	Muco-adherent topical corticosteroid	Gastroenterology	US NDA approval for Eosinophilic Esophagitis	TBD		In active discussions with the FDA. Potential approval subject to outcome of discussions
TAK-007	CD19 CAR-NK	Oncology	Phase 2 study start in Takeda-sponsored trial		<b>✓</b>	Study started, first clinical batch released and FPI expected 3Q
Soticlestat	CH24H inhibitor	Neuroscience	Phase 3 Pivotal study start in Dravet syndrome		<b>✓</b>	
TAK-935	CH24H IIIIIDILOI	Neuroscience	Phase 3 Pivotal study start in Lennox-Gastaut syndrome		<b>✓</b>	
EXKIVITY	EGFR tyrosine kinase		Regulatory filing in China for 2L NSCLC w/ EGFR exon 20 insertion mutations	H1	~	
Mobocertinib	inhibitor	Oncology	US NDA approval for NSCLC patients with EGFR exon 20 insertion mutations who have previously received platinum-based chemotherapy	H2	~	US approval of EXKIVITY September 15 <sup>th</sup>
Pevonedistat	NAE inhibitor	AF inhibitor Oncology	Pivotal study read out in Phase 3 PANTHER study in 1L HR-MDS	H1	×	No plans to file in HR MDS or AML <sup>2</sup>
TAK-924	NAE IIIIIDITOI	Oncology	US NDA submission for patients with HR <sup>-</sup> MDS	H2	•	
Maribavir TAK-620	CMV protein kinase inhibitor	Rare Genetics & Hematology	US NDA approval for post-transplant CMV infection R/R to prior therapy	H2		FDA granted priority review FDA ad com vote in favor of R/R indication
TAK-003	Dengue vaccine	Vaccine	Regulatory approval for Dengue vaccine in EU, and start of regulatory approvals for endemic countries	H2	<b>→</b>	Potential CHMP Opinion expected H2 FY21. Potential EU approval early FY22
TAK-994	Orexin 2 receptor agonist	Neuroscience	Proof-of-concept in Narcolepsy Type 2 Phase 2b readout in Narcolepsy Type 1 Regulatory alignment for Narcolepsy Type 1 Phase 3 development	H2	<b>→</b>	Ph2 trials stopped to assess benefit/risk
			Phase 1 start in healthy volunteers	H1	<b>/</b>	
TAK-861	Orexin 2 receptor agonist	Neuroscience	Phase 1b start in NT1 patients	H2		
TAK-906	D2/D3 receptor antagonist	Gastroenterology	Phase 2b read out in Gastroparesis	H1		Data in-house and under evaluation.
TAK-755	ADAMTS13	Rare Genetics & Hematology	Phase 2 readout in Immune Thrombotic Thrombocytopenic Purpura (iTTP)	H2		
TAK-951	Peptide agonist	Gastroenterology	Proof-of-concept in PONV	H2		
Modakafusp alfa TAK-573	Anti-CD38-attenukine	Oncology	Proof-of-concept in R/R MM	H2	<b>✓</b>	Presentation at a future medical meeting
Subasumstat TAK-981	SUMO inhibitor	Oncology	Early proof-of-concept in multiple cancers	H2		

All timelines are approximate estimates as of October 28, 2021 and are subject to change and subject to regulatory approval. Green tick mark indicates that milestone has been achieved.
 Pevonedistat trials in AML are ongoing but not recruiting new patients and are not registrational.
 Table only shows selected R&D milestones and is not comprehensive. For full glossary of disease abbreviations please refer to appendix.

# **AGENDA**

04.

**Q&A Session** 

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# ACCELERATION OF TOPLINE GROWTH: H1 UNDERLYING REVENUE GROWTH +6.8%



- Confirming full-year FY2021 guidance of "mid-single digit" underlying revenue and underlying Core Operating Profit growth<sup>2</sup>
- Share buyback of up to JPY 100B underscores confidence in business strategy & commitment to delivering value to our shareholders;
   no impact on deleveraging targets

### **FY2021 H1 (APR-SEP)**

**DRIVEN BY 14 GLOBAL BRANDS** 

### **TOPLINE**

- **Underlying Revenue growth +6.8%**¹ driven by acceleration of 14 Global Brands +11.4%; China an important growth driver benefitting from recent innovative product launches
- Reported Revenue JPY 1,794.4B (USD 16.1B)<sup>3</sup> with growth of +12.8% as sale of diabetes portfolio in Japan, growth of 14 Global Brands and favorable FX more than offset divestiture headwinds

### **MARGINS**

- Underlying Core Operating Profit Margin 29.1%¹ with Underlying Core Operating Profit growth of +6.4%
- Core Operating Profit JPY 485.7B (USD 4.4B)<sup>1,3</sup> declining -4.3% mainly due to divestitures
- Reported Operating Profit JPY 346.0 B (USD 3.1B)<sup>3</sup> with growth of +60.5%

### **CASH FLOW**

- Free Cash Flow JPY 315.6B (USD 2.8B)<sup>3,4</sup> on track to full year target of JPY 600-700B
- Net debt / Adjusted EBITDA<sup>5</sup> at 3.1x
- Already paid all debt maturing in FY2021 as well as pre-payment of ~JPY 418B (USD 3.7B)<sup>2</sup> maturing in FY22 and FY25

<sup>1.</sup> Please refer to slide 34 for definition and slides 46 & 48 for reconciliation

<sup>2.</sup> Please refer to slide 28 for FY2021 forecast and guidance

<sup>3.</sup> USD included for reference, calculated at JPY/USD of 111.5

<sup>4.</sup> Please refer to slide 35 for definition and slide 52 for reconciliation

# STRONG TOPLINE GROWTH IN H1, WITH CORE OPERATING PROFIT REFLECTING INCREASED R&D INVESTMENT AND DIVESTITURES



### **FY2021 H1 (APR-SEP) FINANCIAL RESULTS (SUMMARY)**

(BN YEN)	REPO	RTED	СО	UNDERLYING <sup>2</sup>	
	FY2021 H1	VS. PRIOR YEAR	FY2021 H1	VS. PRIOR YEAR	1
REVENUE	1,794.4	+12.8%	1,661.4	+4.4%	+6.8%
OPERATING PROFIT	346.0	+60.5%	485.7	-4.3%	+6.4%
Margin	19.3%	+5.7pp	29.2%	-2.7рр	29.1%
NET PROFIT	183.6	+112.2%	335.9	-2.8%	
EPS (JPY)	117 yen	+111.2%	214 yen	-3.3%	+9.1%
OPERATING CASH FLOW	400.0	+2.0%			
FREE CASH FLOW <sup>3</sup>	315.6	-25.8%			

<sup>1.</sup> Please refer to slide 34 for definition and slide 48 for reconciliation. Core revenue is adjusted to remove JPY 133.0B booked as revenue for the sale of the diabetes portfolio in Japan.

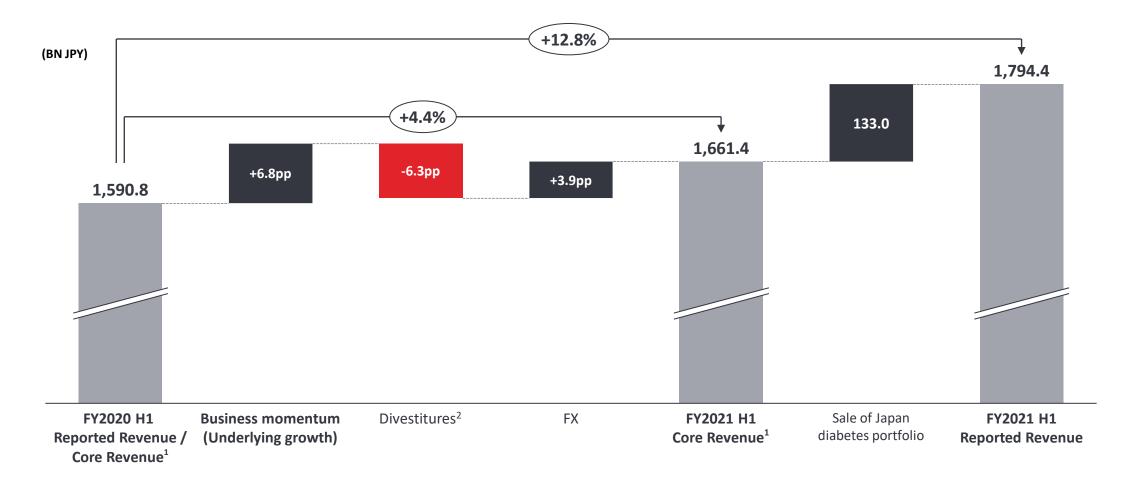
<sup>2.</sup> Please refer to slide 34 for definition and slide 48 for reconciliation

<sup>3.</sup> Please refer to slide 35 for definition and slide 52 for reconciliation

# UNDERLYING REVENUE MOMENTUM DRIVEN BY 14 GLOBAL BRANDS; REPORTED REVENUE BENEFITTING FROM SALE OF DIABETES PORTFOLIO



### **FY2021 H1 REVENUE VS PRIOR YEAR**



#### Graphs are illustrative

<sup>1.</sup> Please refer to slide 34 for definition and slides 48 & 50 for reconciliation

# UNDERLYING REVENUE GROWTH +6.8%¹ SUPPORTED BY 5 KEY BUSINESS AREAS WITH STRONG GROWTH OF PDT, GI, ONCOLOGY & NEUROSCIENCE



#### FY2021 H1 REVENUE<sup>2</sup>



<sup>1.</sup> Please refer to slide 34 for definition and slides 46 & 48 for reconciliation

<sup>2.</sup> Percentage of sales are based on Core revenue; adjusted to remove JPY 133.0B from sale of Japan diabetes portfolio recorded in revenue. Year-on-year growth rates are underlying revenue.

<sup>3.</sup> Takeda is working closely with the FDA on a proposed plan to resupply NATPARA in the U.S., however, at this time we do not expect a return to the U.S. commercial market before March 31, 2022

# PLASMA-DERIVED THERAPIES: ON TRACK TO REVENUE TARGETS & CONSISTENTLY SURPASSING PRE-PANDEMIC DONATION VOLUMES



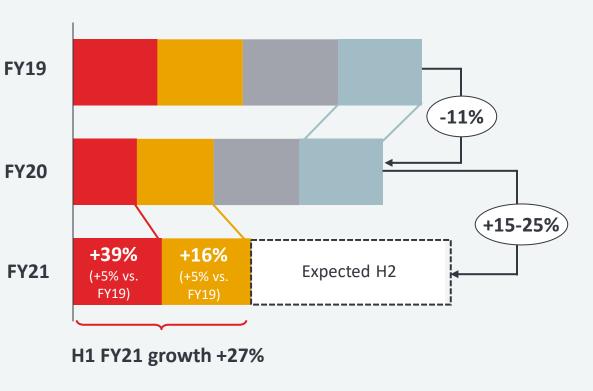
### On track to full-year double digit growth forecast

- PDT Immunology H1 underlying revenue growth +11.1%;
   on track to full-year double digit growth forecast
- Immunoglobulin products H1 underlying revenue growth +8% with quarter-on-quarter phasing impact balanced in Q2; confident in full-year forecast of 5-10% growth
- Albumin portfolio exhibited strong H1 underlying revenue growth of +35%

### **Consistently surpassing pre-pandemic donation volumes**

- FY2021 H1 plasma donation volume +27% versus prior year;
   +5% versus pre-pandemic FY2019 levels
- Revised plasma donation growth projection to +15-25% for FY2021, the volume needed to meet patient supply commitments and revenue growth target, while improving network efficiency, managing donor fees and cost of goods

### **PLASMA DONATION VOLUMES**





Graph is illustrative. Source: Takeda internal data

# 14 GLOBAL BRANDS +11.4% UNDERLYING GROWTH, REPRESENTING 42% OF FY2021 H1 CORE REVENUE<sup>1</sup>



## **14 GLOBAL BRANDS FY2021 H1 TOTAL: JPY 692.2B (US\$6.2B2)** +JPY 96.3B (US\$ 864M<sup>2</sup>) VS PRIOR YEAR

FY20	21 H1 REVENUE	(BN JPY)	(MM USD)	versus PY (underlying)
	<b>Entyvio</b> <sup>*</sup> vedolizumab	255.9	2,295	+18.1%
	Gattex (Teduglutide (FDNA origin)) for Injection	36.8	330	+6.9%
	∧ L FIS≣L	0.8	7	+166.8%
$\bigcirc$	IMMUNOGLOBULIN	181.3	1,626	+8.0%
		GAMMAGARD LIQUID [Immune Globulin Intravenous (Human)] 10%	Kiovig men Normal Immunoglobulin (Mgl.) 10% Solution	+7.4%
		HyQvio Human Normal Immu Recombinant Human	noglobulin (10%)	+4.4%
		Cuvit (Immune Globulin Su	CTU bcutaneous (Human)] 20%	+21.2%
	ALBUMIN/FLEXBUMIN	N <sup>3</sup> 41.7	374	+35.0%

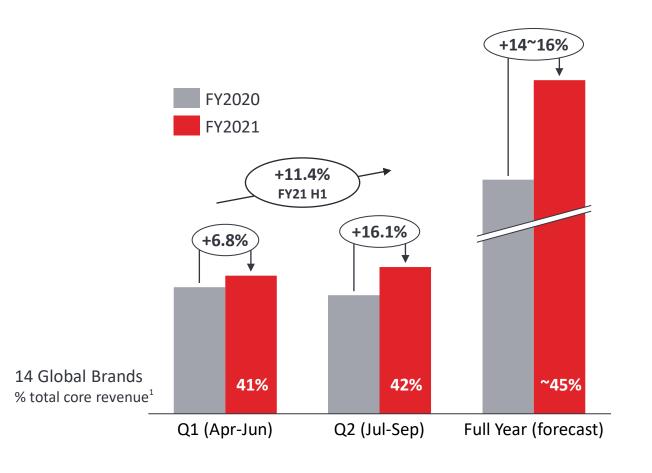
FY2021	H1 REVENUE	(BN JPY)	(MM USD)	versus PY (underlying)
%;	NINLARO (ixazomib) capsules	45.8	411	-1.1%
	ALUNBRIG BRIGATINIB	6.2	56	+39.7%
Alle	TAKHZYRO (lanadelumab-flyo) injection	47.5	426	+4.7%
	ADYNOVATE  Rurioctocog alfa pegol (Recombinant Cosquidation Factor VIII)	30.0	269	-2.1%
	<b>%</b> Natpara	2.5	22	+50.4%
	elaprase (idursulfase)	34.8	312	-1.5%
		21.0	188	+7.2%

Percentage of sales are based on Core revenue; adjusted to remove JPY 133.0B from sale of Japan diabetes portfolio recorded in revenue. Year-on-year growth rates are underlying revenue.
 USD included for reference calculated at JPY/USD of 111.5 yen
 Total includes Albumin Glass, Flexbumin and Kenketsu Albumin.

## **GROWTH MOMENTUM OF 14 GLOBAL BRANDS EXPECTED TO CONTINUE**



### 14 GLOBAL BRANDS GROWTH RATE & PERCENTAGE OF REVENUE<sup>1</sup>



# FY2021 H1 underlying revenue growth of +11.4%; acceleration expected in H2

- Q2 underlying growth (+16.1%) accelerated from Q1 (+6.8%)
- 14 Global Brands H1 underlying growth in all regions
  - U.S. +8%
  - Europe & Canada +15%
  - Japan +9%
  - Growth & Emerging Markets +31%
- Further tailwinds anticipated in H2 due to albumin supply timing in China
- 14 Global Brands expected to represent ~45% of core revenue in FY2021 compared to 38% in FY2020 and 34% in FY2019

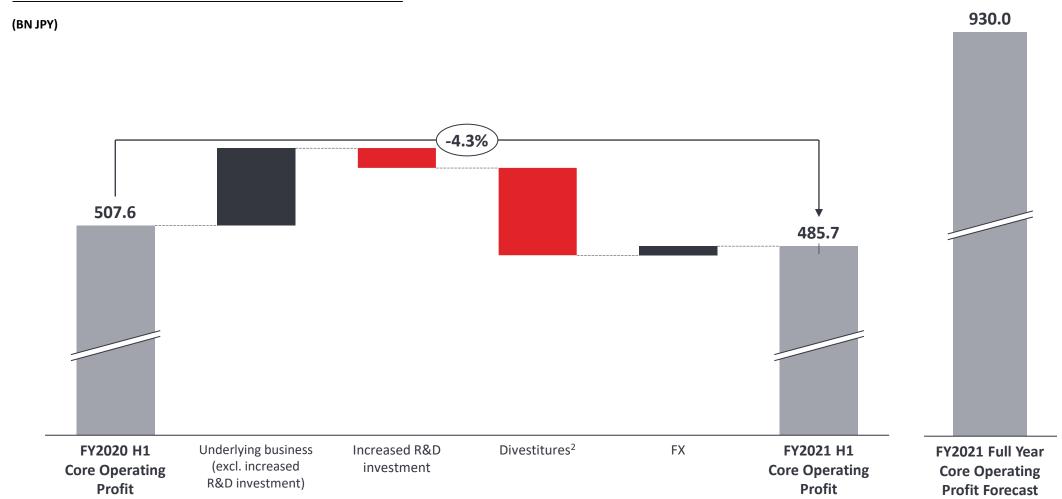
### **Growth momentum expected to continue beyond FY2021**

- Continued market penetration in launched countries
- Expanding market size through disease awareness
- Geographic expansion, including Japan, China and Emerging Markets

# CORE OPERATING PROFIT REFLECTS INCREASE IN R&D INVESTMENT & DIVESTITURE IMPACT; ON TRACK TO FULL YEAR FORECAST OF JPY 930B



### FY2021 H1 CORE OPERATING PROFIT<sup>1</sup>



#### Graphs are illustrative

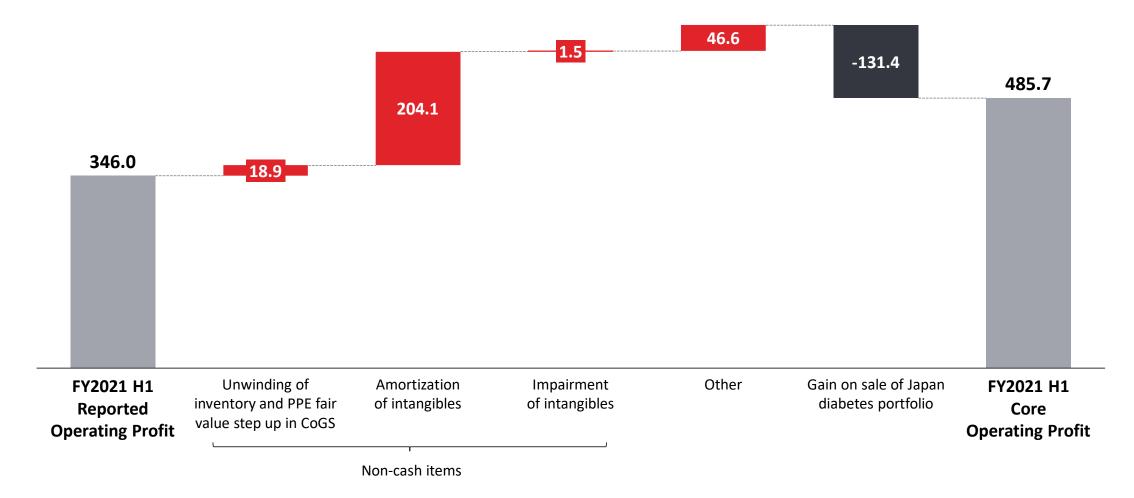
- 1. Please refer to slide 34 for definition and slides 48 & 50 for reconciliation
- 2. Refers to Operating Profit attributable to divested businesses; does not include gain on divestitures, which is adjusted out of Core Operating Profit

# REPORTED OPERATING PROFIT REFLECTS DECLINING PPA & INTEGRATION COSTS, ALSO GAIN ON SALE OF JAPAN DIABETES PORTFOLIO



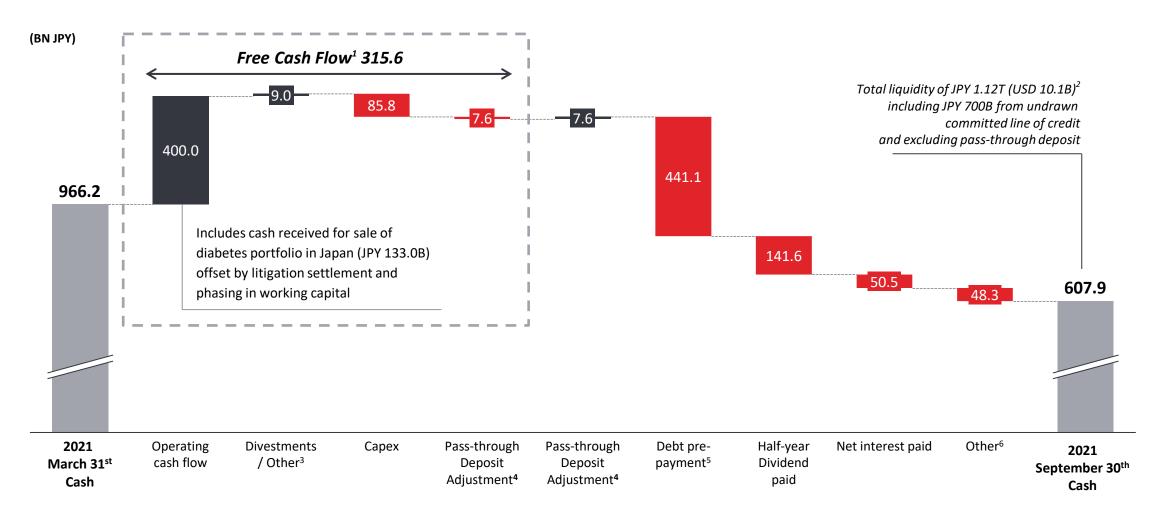
### BRIDGE FROM H1 REPORTED TO CORE OPERATING PROFIT<sup>1</sup>

(BN JPY)



## FY2021 H1 CASHFLOW REFLECTS SIGNIFICANT DEBT PRE-PAYMENT





<sup>1.</sup> Please refer to slide 35 for definition and slide 52 for reconciliation

<sup>2.</sup>USD provided for reference calculated at JPY/USD of 111.5 yen

<sup>3.</sup> Proceeds from Divestments are net of non-equity method of investments

<sup>4.</sup> Pass-through Deposit Adjustment refers to deposits restricted to certain vaccine operations included in Operating Cash Flow but removed from Free Cash Flow because cash is not available for Takeda's immediate or general business use.

<sup>5. &</sup>quot;Debt Repayment" comprises debt pre-payment of JPY 220.1B (USD 2B) JBIC Loan, JPY 198.2B (EUR 1.5B) EUR Bond and JPY 22.8B (USD 0.2B) USD Bonds including debt reduction premium

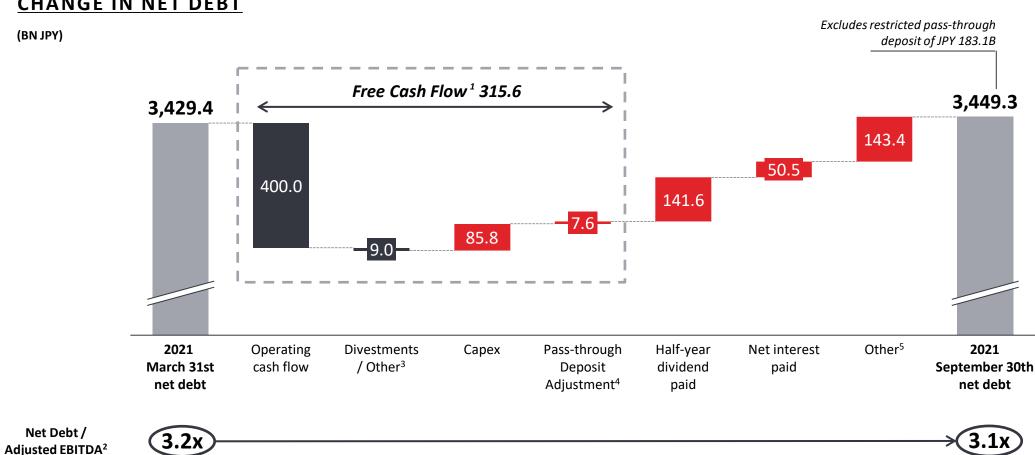
<sup>6. &</sup>quot;Other" indicates items such as FX impact on cash, lease obligations, acquisition of business, equity method investments and contingent considerations payments.

JBIC: Japan Bank for International Cooperation

# **NET DEBT/ADJUSTED EBITDA AT 3.1x**



### **CHANGE IN NET DEBT**



converting non-JPY debt into JPY.

<sup>1.</sup> Please refer to slide 35 for definition and slide 52 for reconciliation

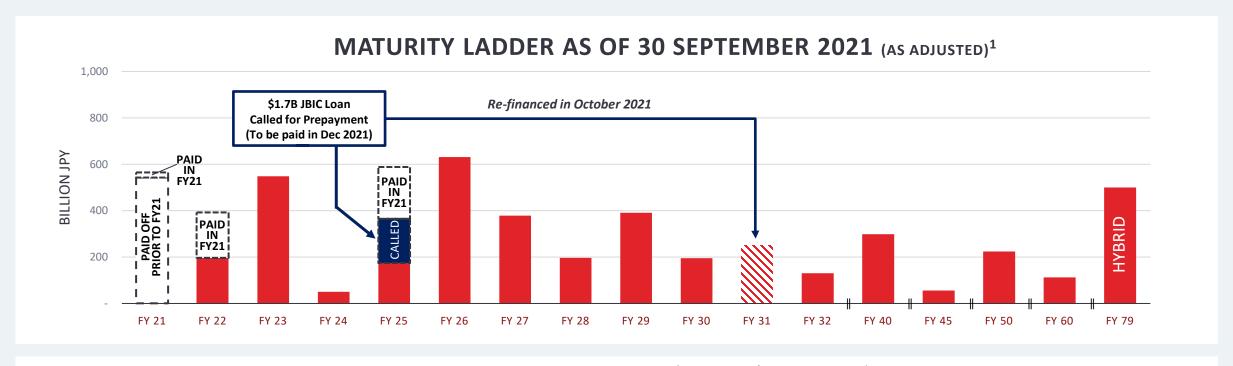
<sup>2. &</sup>quot;Adjusted EBITDA" mainly adjusts for non cash items and one-time expenses. Please refer to slide 36 for definition and slides 53-55 for reconciliation.

<sup>3.</sup> Proceeds from divestments are net of non-equity method investments

<sup>4.</sup> Pass-through deposit adjustment refers to deposits restricted to certain vaccine operations included in Operating Cash Flow but removed from Free Cash Flow and net debt because this cash is not available for Takeda's immediate or general business use. 5. Includes cash and non cash adjustments to debt book-value and equity method investments, acquisition of business and contingent consideration payments. Non cash adjustments include changes due to debt amortization and FX impact from

# WELL POSITIONED MATURITY PROFILE FACILITATES COMFORTABLE PAYMENT OF DIVIDENDS OVER TIME





Weighted Average Interest Coupon: ~2% (over 90% fixed rate debt)

FY2021 Q2: Prepaid EUR 1.5B November 2022 Bond; Called \$1.7B of JBIC Loan (to be paid in December 2021)

FY2021 H1: Prepaid JPY 441B (~\$4B) of debt principal (not including called \$1.7B JBIC Loan)

October 2021: Issued JPY 250B 0.4% Bond due 2031 primarily to re-finance the \$1.7B JBIC Loan

# CONFIRMING FULL-YEAR FY2021 GUIDANCE OF "MID-SINGLE DIGIT" UNDERLYING REVENUE AND UNDERLYING CORE OPERATING PROFIT GROWTH



(BN YEN)	FY2021 ORIGINAL FORECAST (MAY 2021)	FY2021 CURRENT FORECAST (OCT 2021)	UNDERLYING <sup>2</sup> (MANAGEMENT GUIDANCE) (UNCHANGED FROM MAY 2021)
REPORTED REVENUE	3,370.0	3,370.0	Mid-single-digit growth
R&D EXPENSES	-522.0	-522.0	
REPORTED OPERATING PROFIT	488.0	488.0	
CORE OPERATING PROFIT <sup>1</sup>	930.0	930.0  Revised to reflect tax provision related to	Mid-single-digit growth ~30% margin
REPORTED EPS (YEN)	160	AbbVie break fee booked in Q1	
CORE EPS (YEN)	394	394	Mid-single-digit growth
FREE CASH FLOW	600-700	600-700	
ANNUAL DIVIDEND PER SHARE (YEN)	180	180	

#### Key assumptions in FY2021 forecast:

(1) To date, Takeda has not experienced a material effect on its financial results as a result of the global spread of the novel coronavirus infectious disease (COVID-19). Based on currently available information, Takeda believes that its financial results for FY2021 will not be materially affected by COVID-19 and, accordingly, Takeda's FY2021 forecast reflects this belief. However, the situation surrounding COVID-19 remains highly fluid, and future COVID-19-related developments in FY2021, including new or additional COVID-19 outbreaks and additional or extended lockdowns, shelter-in-place orders or other government action in major markets, could result in further or more serious disruptions to Takeda's business, such as slowdowns in demand for Takeda's products, supply chain related issues or significant delays in its clinical trial programs. These events, if they occur, could result in an additional impact on Takeda's business, results of operations or financial condition, as well as result in significant deviations from Takeda's FY2021 forecast.

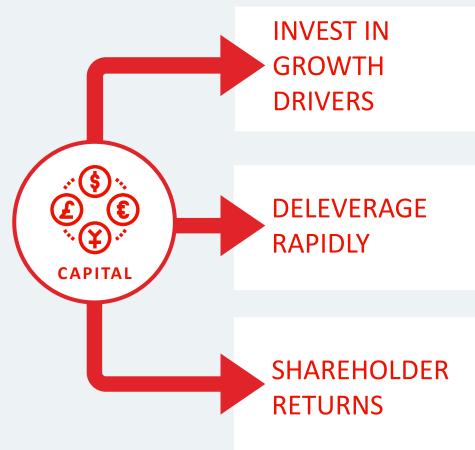
(2) Takeda expects at least one 505(b)2 competitor for subcutaneous VELCADE to launch in the U.S. around mid FY2021

- (3) Takeda does not expect to restart sales of Natpara in the U.S. market in FY2021
- (4) FY2021 guidance does not include the impact of any potential further divestitures beyond what has already been disclosed by Takeda
- 1. Please refer to slide 34 for definition and slide 58 for FY2021 forecast reconciliation.
- 2. Underlying growth adjusts for divestitures (assets divested in FY2020 and disclosed divestitures expected to close in FY2021) and applies the FY2020 full year average FX rate. Please refer to slide 34 for definition.

# **CAPITAL ALLOCATION TO MAXIMIZE VALUE FOR PATIENTS & SHAREHOLDERS**



Takeda is delivering on its financial commitments and has a strong cash flow outlook driven by revenue growth and strong margins. Guided by our values and commitment to patients, people and the planet, we will allocate capital to maximize value for patients & shareholders.



- Strategic investment in R&D (in-house and partnerships)
- New product launches, including in China
- Plasma-Derived Therapies
- Net Debt / Adjusted EBITDA<sup>1</sup> ratio to reach 2x (i.e. "low-twos") within fiscal years ending March 2022 – March 2024
- Maintain solid investment grade credit ratings
- Underlying growth momentum expected to continue over the mid-term
- Return cash to shareholders: maintain well-established dividend policy of 180 yen per share annually, alongside share buybacks when appropriate

# ACCELERATION OF TOPLINE GROWTH: H1 UNDERLYING REVENUE GROWTH +6.8%



### **FY2021 H1 (APR-SEP)**

**DRIVEN BY 14 GLOBAL BRANDS** 

#### **FY2021 AND BEYOND**

TOPLINE

Underlying Revenue growth +6.8%<sup>1</sup>

- Confirming full year FY2021 guidance of "mid-single digit" underlying revenue growth driven by strength of 14 Global Brands
- Momentum expected to continue driven by 14 Global Brands, new product launches, and continued roll-out of COVID-19 vaccines

**MARGINS** 

Core Operating Profit<sup>2</sup> JPY 485.7B Underlying Core OP<sup>2</sup> margin 29.1%

- Tracking well towards full-year FY2021 Core Operating Profit forecast of JPY 930.0B and full-year margin guidance
- Target "low-to-mid thirties" margins in FY2021-2023

**CASH FLOW** 

Free Cash Flow<sup>3</sup> JPY 315.6B Net Debt/Adjusted EBITDA<sup>4</sup> 3.1x

- On track to full year Free Cash Flow<sup>3</sup> target of JPY 600-700B
- Continued focus on debt paydown, while investing in growth drivers and returning cash to shareholders
- Target 2x ("low twos") Net debt / Adjusted EBITDA⁴ ratio in fiscal years ending March 2022 – March 2024

<sup>1.</sup> Please refer to slide 34 for definition and slides 46 & 48 for reconciliation

<sup>2.</sup> Please refer to slide 34 for definition and slide 46 for reconciliation

<sup>3.</sup> Please refer to slide 35 for definition and slide 52 for reconciliation



# Q&A SESSION



Christophe Weber
President & Chief
Executive Officer



Andy Plump

President, Research &

Development



Costa Saroukos
Chief Financial Officer



Masato Iwasaki
Japan General Affairs



Ramona Sequeira

President, U.S. Business
Unit & Global Portfolio
Commercialization



**Julie Kim**President, Plasma-Derived
Therapies Business Unit



# **APPENDIX**



## **TAKEDA'S DISCLOSURE METRICS**



### "REPORTED"

Financial results recorded and prepared in accordance with International Financial Reporting Standards (IFRS)

### "CORE"

From Reported Results, adjust for:

- 1. Amortization and impairment expenses for intangible assets associated with products
- 2. Impacts of purchase accounting
- 3. Restructuring costs
- 4. Other material or non-recurring items that do not represent our on-going core operations (e.g. one-time expenses & income)

Intended to be similar to 'Non-GAAP' or 'Core' results reported by our peers

## "UNDERLYING"

From Core Results, further adjust for:

- 1. Impact of foreign exchange
- Impact of divestitures (divested assets removed from both prior and current year)

GAAP Reporting (IFRS)

Non-GAAP Reporting (Non-IFRS)

## **DEFINITION OF CORE AND UNDERLYING GROWTH**



Takeda uses the concept of Underlying Growth for internal planning and performance evaluation purposes.

Underlying Growth compares two periods (fiscal quarters or years) of financial results under a common basis and is used by management to assess the business. These financial results are calculated on a constant currency basis using a full year plan rate and exclude the impacts of divestitures and other amounts that are unusual, non-recurring items or unrelated to our ongoing operations. Although these are not measures defined by IFRS, Takeda believes Underlying Growth is useful to investors as it provides a consistent measure of our performance.

Takeda uses "Underlying Revenue Growth", "Underlying Core Operating Profit Growth", and "Underlying Core EPS Growth" as key financial metrics.

**Underlying Revenue** represents revenue on a constant currency basis and excluding non-recurring items and the impact of divestitures that occurred during the reporting periods presented.

**Underlying Core Operating Profit** represents Core Operating Profit (as defined to the right) on a constant currency basis and further adjusted to exclude the impacts of divestitures that occurred during the reporting periods presented.

**Underlying Core EPS** represents net profit based on a constant currency basis, adjusted to exclude the impact of divestitures and items excluded in the calculation of Core EPS (as defined to the right), divided by the outstanding shares (excluding treasury shares) as of the end of the comparative period.

**Core Revenue** represents revenue adjusted to exclude significant items unrelated to Takeda's core operations.

**Core Operating Profit** represents net profit adjusted to exclude income tax expenses, the share of profit or loss of investments accounted for using the equity method, finance expenses and income, other operating expenses and income, amortization and impairment losses on acquired intangible assets and other items unrelated to Takeda's core operations, such as non-recurring items, purchase accounting effects and transaction related costs.

**Core EPS** represents net profit adjusted to exclude the impact of items excluded in the calculation of Core Operating Profit, and other non-operating items (e.g. amongst other items, fair value adjustments and the imputed financial charge related to contingent consideration) that are unusual, non-recurring in nature or unrelated to Takeda's ongoing operations and the tax effect of each of the adjustments, divided by the average outstanding shares (excluding treasury shares) of the reporting periods presented.

# **DEFINITION OF FREE CASH FLOW**



We present Free Cash Flow because we believe that this measure is useful to investors as similar measures of liquidity are frequently used by securities analysts, investors and other interested parties in the evaluation of companies in our industry. Free Cash Flow is also used by our management to evaluate our liquidity and our cash flows, particularly as they relate to our ability to meet our liquidity requirements and to support our capital allocation policies. We also believe that Free Cash Flow is helpful to investors in understanding how our strategic divestitures of non-core businesses and of portions of our investment portfolio contribute to the cash flows and liquidity available to us.

We define Free Cash Flow as cash flows from operating activities, excluding acquisition of property, plant and equipment, intangible assets and investments, and any other cash that is not available to Takeda's immediate or general business use, and including proceeds from sales of property, plant, sales and redemption of investments and businesses, net of cash and cash equivalents divested.

The usefulness of Free Cash Flow to investors has significant limitations including, but not limited to, (i) it may not be comparable to similarly titled measures used by other companies, including those in our industry, (ii) it does not reflect the effect of our current and future contractual and other commitments requiring the use or allocation of capital and (iii) the inclusion of proceeds from sales and redemption of investments and the proceeds from sales of business, net of cash and cash equivalents divested, although they reflect the execution of our current strategy of divesting non-core assets, do not reflect cash received from our core ongoing operations. Free Cash Flow should not be considered in isolation and is not, and should not be viewed as, a substitute for cash flows from operating activities or any other measure of liquidity presented in accordance with IFRS. The most directly comparable measure under IFRS for Free Cash Flow is net cash from operating activities.

# **DEFINITION OF EBITDA/ADJUSTED EBITDA AND NET DEBT**



#### **EBITDA and Adjusted EBITDA**

We present EBITDA and Adjusted EBITDA because we believe that these measures are useful to investors as they are frequently used by securities analysts, investors and other interested parties in the evaluation of companies in our industry. We further believe that Adjusted EBITDA is helpful to investors in identifying trends in its business that could otherwise be obscured by certain items unrelated to ongoing operations because they are highly variable, difficult to predict, may substantially impact our results of operations and may limit the ability to evaluate our performance from one period to another on a consistent basis.

EBITDA and Adjusted EBITDA should not be considered in isolation or construed as alternatives to operating income, net profit for the year or any other measure of performance presented in accordance with IFRS. These non-IFRS measures may not be comparable to similarly-titled measures presented by other companies.

The usefulness of EBITDA and Adjusted EBITDA to investors has limitations including, but not limited to, (i) they may not be comparable to similarly titled measures used by other companies, including those in our industry, (ii) they exclude financial information and events, such as the effects of an acquisition or amortization of intangible assets, that some may consider important in evaluating our performance, value or prospects for the future, (iii) they exclude items or types of items that may continue to occur from period to period in the future and (iv) they may not exclude all items which investors may consider to be unrelated to our long-term operations, such as the results of businesses divested during a period. These non-IFRS measures are not, and should not be viewed as, substitutes for IFRS reported net income (loss). We encourage investors to review our historical financial statements in their entirety and caution investors to IFRS measures as the primary means of evaluating our performance, value and prospects for the future, and EBITDA and Adjusted EBITDA as supplemental measures.

We define EBITDA as net profit before income tax expenses, depreciation and amortization and net interest expense. We define Adjusted EBITDA as EBITDA further adjusted to exclude impairment losses, other operating expenses and income (excluding depreciation and amortization), finance expenses and income (excluding net interest expense), our share of loss from investments accounted for under the equity method and other items that management believes are unrelated to our core operations such as purchase accounting effects and transaction related costs.

The most closely comparable measure presented in accordance with IFRS is net profit for the year. Please refer to slides 54-55 for a reconciliation to the respective most closely comparable measures presented in accordance with IFRS.

#### **Net Debt**

We present Net Debt because we believe that it is useful to investors in that our management uses it to monitor and evaluate our indebtedness, net of cash and cash equivalents, and, in conjunction with Adjusted EBITDA, to monitor our leverage. We also believe that similar measures of indebtedness are frequently used by securities analysts, investors and other interested parties in the evaluation of companies in our industry.

We define Net Debt first by calculating the sum of the current and non-current portions of bonds and loans as shown on our consolidated statement of financial position, which is then adjusted to reflect (i) the use of prior 12-month average exchange rates for non-JPY debt outstanding at the beginning of the period and the use of relevant spot rates for new non-JPY debt incurred and existing non-JPY debt redeemed during the reporting period, which reflects the methodology our management uses to monitor our leverage, and (ii) a 50% equity credit applied to our aggregate principal amount of 500.0 billion hybrid (subordinated) bonds issued in June 2019 by S&P Global Rating Japan in recognition of the equity-like features of those bonds pursuant to such agency's ratings methodology. From this figure, we deduct cash and cash equivalents, excluding cash that is not available to Takeda's immediate or general business use, to calculate Net Debt.

The usefulness of Net Debt to investors has significant limitations including, but not limited to, (i) it may not be comparable to similarly titled measures used by other companies, including those in our industry, (ii) it does not reflect the amounts of interest payments to be paid on our indebtedness, (iii) it does not reflect any restrictions on our ability to prepay or redeem any of our indebtedness, (iv) it does not reflect any fees, costs or other expenses that we may incur in converting cash equivalents to cash, in converting cash from one currency into another or in moving cash within our consolidated group, (v) it applies to gross debt an adjustment for average foreign exchange rates which, although consistent with our financing agreements, does not reflect the actual rates at which we would be able to convert one currency into another and (vi) it reflects an equity credit due to the fact that the amounts of our subordinated bonds, although we believe it to be reasonable, do not affect the status of those instruments as indebtedness. Net Debt should not be considered in isolation and are not, and should not be viewed as, a substitute for bonds and loans or any other measure of indebtedness presented in accordance with IFRS.

The most directly comparable measures under IFRS for Net Debt is bonds and loans. Please refer to slide 53 for a reconciliation to this measure.

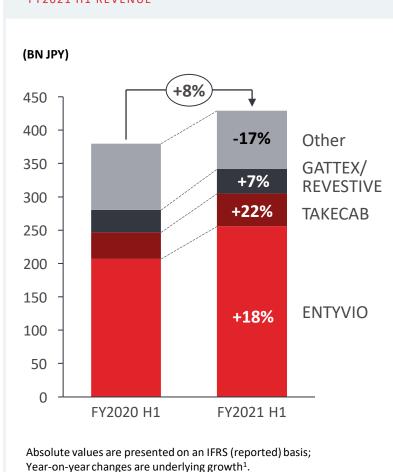


### **GROWTH OF GI FRANCHISE SPEARHEADED BY ENTYVIO**



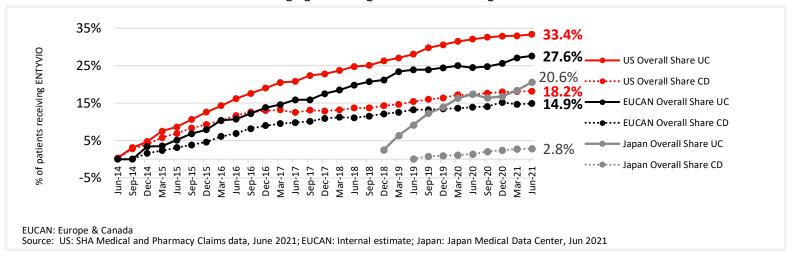
#### **GI PORTFOLIO**

FY2021 H1 REVENUE



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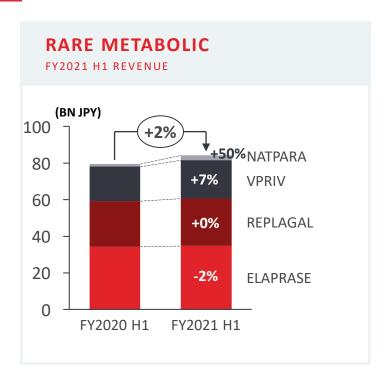
- Entyvio has a gut-selective mechanism of action, and continues to capture patient share in IBD supported by its differentiated efficacy and safety profile (including H2H superiority, real world evidence, endoscopic, histologic, transmural outcomes)
- US: Moving into its 8<sup>th</sup> year on the market, overall growth is still +16% in FY2021 H1 vs prior year.
   Entyvio has achieved leadership in overall IBD bio-naïve share and maintains solid leadership in UC new patient starts.
  - Through our ongoing interactions with the FDA, Takeda has received feedback which has
    provided clarity on the regulatory package and critical elements for submission of a BLA for
    Entyvio subcutaneous (SC) as maintenance therapy in adults with moderate to severe
    ulcerative colitis, and we are moving forward accordingly. We are reviewing our
    development program timelines and currently anticipate potential approval in FY2023.
- EUCAN: Strong growth of +18% FY2021 H1 vs prior year. SC launches continue across region (5 this quarter), those with strong SC uptake driving incremental growth.
- JP: Market leadership achieved in UC this quarter with total growth rate +34%.
- Growth & Emerging Markets growth rate including China +48%.



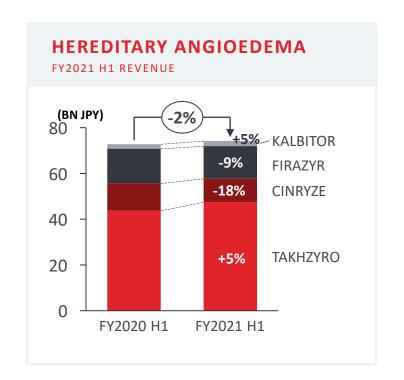


## Takeda

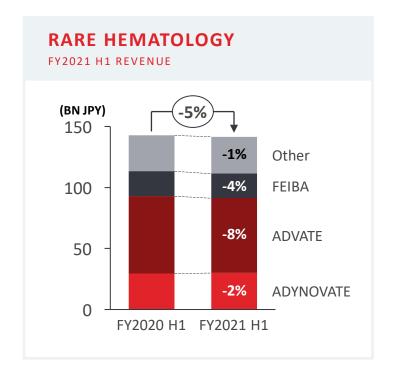
## RARE DISEASES REVENUE IN LINE WITH PLAN; STRONG OUTLOOK FOR TAKHZYRO DRIVEN BY UNIQUE EFFICACY PROFILE



- Lysosomal Storage Diseases: Consistent performance through increased patient finding and utilization; partially offset with shipment timing in some countries
- NATPARA growth from expansion in Europe. In the U.S., Takeda submitted a Prior Approval Supplement (PAS) in August 2021 to address the underlying reason for the U.S. recall (rubber particles originating from the septum). No expected US relaunch of NATPARA before April 2022



- TAKHZYRO H1 growth fueled by successful launches with strong patient uptake, impacted by U.S. channel dynamics; remain on track toward full year forecast of 20-30% underlying growth
  - U.S. market leader, driven by combination of strong efficacy, long-term safety profile and reduced treatment burden
  - Now available in 33 countries worldwide, with further 9 launches planned in H2
- Geographic expansion strategy for CINRYZE



- Rare hematology competitive landscape continues to be in line with expectations
- On track following China NDA submission of ADYNOVATE and acceptance by CDE in June 2021
- In Q2 2021: submitted for significant ADYNOVATE tender in Canada
- In Q2 2021: won FEIBA tender in Poland; submitted important FEIBA tenders in Ukraine, India and other markets with supply starting FY2021

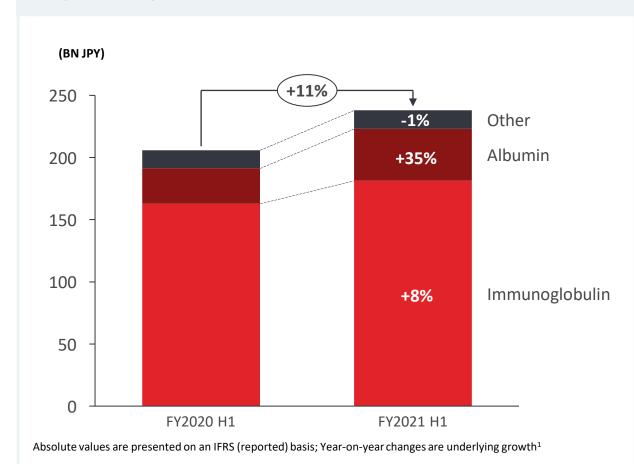




### PDT PORTFOLIO ON TRACK TO FULL-YEAR DOUBLE DIGIT GROWTH FORECAST



FY2021 H1 REVENUE



GAMMAGARD LIQUID [Immune Globulin Intravenous (Human)] 10%







- Immunoglobulin products underlying growth +8% in H1, with quarter-on-quarter phasing impact balanced in Q2; we remain confident in full-year forecast of 5-10% growth
- Albumin portfolio exhibited strong growth, up +35%

#### **CONTINUING TO INVEST IN PLASMA DONATION**

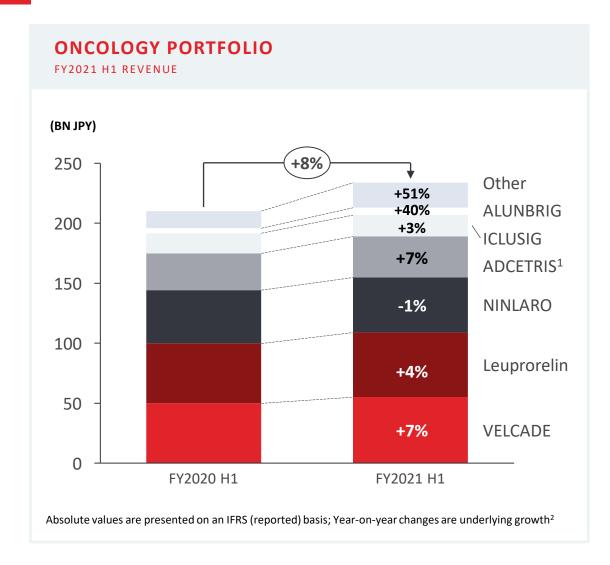
- FY21 H1 plasma volume +27% versus prior year, and consistently surpassing pre-pandemic donation levels since FY2021 Q1.
- As of Sep 30th, our current footprint is 193 centers (160 centers in the US and 33 in the EU); on track to add >20 centers in FY2021, for a total of 200+ centers by FY end
- Execution against strategy to invest in new centers and enhance operational excellence across entire network to increase plasma supply and manufacturing capacity by >65% by end of FY2023<sup>2</sup> is on track

<sup>1.</sup> For definition please refer to slide 34.

<sup>2.</sup> Versus 2018 baseline



### STRONG ONCOLOGY PORTFOLIO CONTINUES TO EXPAND INDICATIONS





Received Accelerated Approval from the U.S. FDA in September 2021 for the treatment of patients with locally advanced or metastatic NSCLC with EGFR Exon20 insertion mutations who were previously treated with platinumbased chemotherapy.



- Strong growth in Japan driven by continued uptake in the maintenance setting, as well as sustained performance within the relapsed / refractory setting.
- Impacted by COVID-19 treatment dynamics including temporary U.S. uptick in FY20 due to move to oral treatment at height of pandemic. Practices have now returned to pre-COVID prescribing habits.



Published positive final analysis from ALTA 1L at ESMO, confirming the benefit of ALUNBRIG versus crizotinib in firstline ALK+ NSCLC.



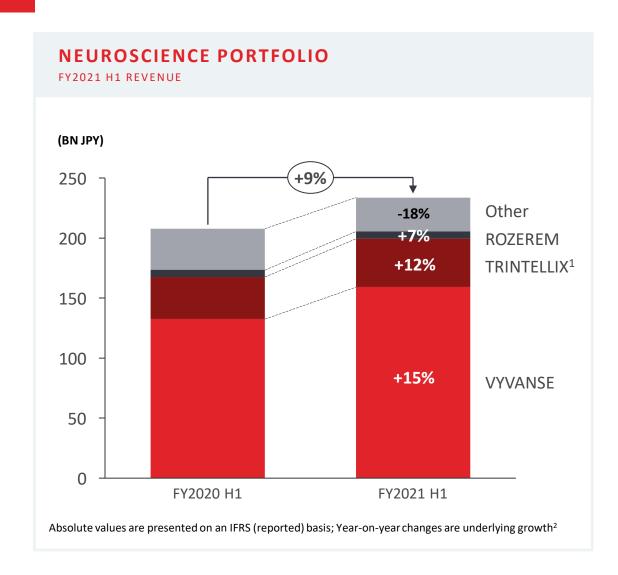
Continued growth supported by U.S. sNDA approval in December 2020 for adult patients with CP-CML with resistance or intolerance to at least two prior TKIs.

<sup>1.</sup> ADCETRIS is in-licensed from Seagen Inc.; Takeda has development and marketing rights outside of the U.S. and Canada 40 2. For definition please refer to slide 34.





### **VYVANSE REBOUNDING FROM COVID-19 IMPACT IN PRIOR YEAR**





- Vyvanse strong growth reflects continued investment in the growing adult space driving re-acceleration to above pre-COVID expectations in FY2021 as a first-line treatment option.
- Pediatric written request in the US was completed and approved by FDA, providing 6 months additional market exclusivity. We now expect loss of exclusivity in the U.S. to occur in late August 2023.



- As patient flow and the MDD market return to pre-COVID levels, we expect promotional effectiveness to increase over time as we re-engage and help navigate shifts in prescribing habits.
- In Japan, the number of doctors prescribing Trintellix increased by approx. 20% compared to Q4 FY2020. As an increasing number of psychiatrists choosing Trintellix as a first-line treatment, stronger positioning is being established.

- TRINTELLIX is in-licensed from Lundbeck; Takeda has co-marketing rights in the U.S. and Japan.
   For definition please refer to slide 34.

### **FY2021 H1 REPORTED RESULTS**



(BN JPY)	FY2020 H1	FY2021 H1	vs. PY		
Revenue	1,590.8	1,794.4	+203.6	+12.8 %	
Cost of sales	-487.7	-517.1	-29.3	-6.0 %	
Gross Profit	1,103.1	1,277.4	+174.3	+15.8 %	
Margin	69.3 %	71.2 %		+1.8 pp	
SG&A expenses	-418.6	-431.9	-13.2	-3.2 %	
R&D expenses	-225.0	-254.1	-29.1	-12.9 %	
Amortization of intangible assets	-206.0	-204.1	+1.9	+0.9 %	
Impairment losses on intangible assets	-2.1	-1.5	+0.7	+30.9 %	
Other operating income	69.5	19.5	-49.9	-71.9 %	
Other operating expenses	-105.2	-59.4	+45.8	+43.5 %	
Operating profit	215.6	346.0	+130.4	+60.5 %	
Margin	13.6 %	19.3 %		+5.7 pp	
Finance income	29.6	46.9	+17.3	+58.3 %	
Finance expenses	-110.7	-104.9	+5.8	+5.2 %	
Equity income/loss	-8.9	-3.5	+5.4	+60.5 %	
Profit before tax	125.6	284.4	+158.9	+126.5 %	
Net profit attributable to owners of the Company	86.5	183.6	+97.1	+112.2 %	
Non-controlling interests	0.0	0.1	0.0	+76.6 %	
Net profit for the period	86.6	183.7	+97.1	+111.2 %	
Basic EPS (yen)	55	117	+62	+111.2 %	

## FY2021 Q2 (Jul-Sep) REPORTED RESULTS



(BN JPY)	FY2020 Q2 (Jul-Sep)	FY2021 Q2 (Jul-Sep)	vs. PY	
Revenue	788.9	844.8	+55.9	+7.1 %
Cost of sales	-249.6	-275.8	-26.2	-10.5 %
Gross Profit	539.3	569.0	+29.7	+5.5 %
Margin	68.4 %	67.4 %		-1.0 pp
SG&A expenses	-216.3	-212.0	+4.2	+2.0 %
R&D expenses	-118.2	-131.6	-13.4	-11.4 %
Amortization of intangible assets	-103.6	-101.3	+2.4	+2.3 %
Impairment losses on intangible assets	-0.2	-1.5	-1.3	-578.9 %
Other operating income	5.7	8.4	+2.7	+46.9 %
Other operating expenses	-58.5	-33.7	+24.8	+42.4 %
Operating profit	48.3	97.4	+49.1	+101.7 %
Margin	6.1 %	11.5 %		+5.4 pp
Finance income	10.0	6.9	-3.2	-31.5 %
Finance expenses	-63.9	-39.7	+24.2	+37.9 %
Equity income/loss	0.8	-3.2	-4.0	<u>-</u>
Profit before tax	-4.7	61.4	+66.2	-
Net profit attributable to owners of the Company	4.0	46.0	+41.9	-
Non-controlling interests	0.0	0.0	-0.0	-7.3 %
Net profit for the period	4.1	46.0	+41.9	-
Basic EPS (yen)	3	29	+27	-

## FY2021 H1 CORE RESULTS<sup>1</sup>



(BN JPY)	FY2020 H1	FY2021 H1	vs. PY	
Revenue	1,590.8	1,661.4	+4.4 %	
Gross Margin	72.3%	70.3%	-2.1 pp	
Operating expenses	-642.8	-681.5	-6.0 %	
% of Revenue	40.4%	41.0%	-0.6 pp	
Core Operating profit	507.6	485.7	-4.3 %	
Margin	31.9%	29.2%	-2.7 pp	
Core tax rate	22.5%	21.9%	+0.6 pp	
Core Net profit	345.5	335.9	-2.8 %	
Core EPS (yen)	221	214	-3.3 %	

## FY2021 Q2 (Jul-Sep) CORE RESULTS<sup>1</sup>



(BN JPY)	FY2020 Q2 (Jul-Sep)	FY2021 Q2 (Jul-Sep)	vs. PY	
Revenue	788.9	844.8	+7.1 %	
Gross Margin	71.0%	68.5%	-2.5 pp	
Operating expenses	-333.3	-341.7	-2.5 %	
% of Revenue	42.2%	40.5%	+1.8 pp	
Core Operating profit	226.7	236.8	+4.4 %	
Margin	28.7%	28.0%	-0.7 pp	
Core tax rate	19.5%	23.0%	-3.5 pp	
Core Net profit	154.9	159.3	+2.8 %	
Core EPS (yen)	99	101	+2.3 %	

# RECONCILIATION FROM REPORTED REVENUE TO CORE/UNDERLYING REVENUE FY2021 H1 VERSUS PRIOR YEAR



(BN JPY)	FY2020 H1	FY2021 H1	vs. PY		
Reported Revenue	1,590.8	1,794.4	+203.6	+ 12.8%	
Sale of Japan diabetes portfolio <sup>2</sup>	_	-133.0	-133.0	-8.4pp	
Core Revenue	1,590.8	1,661.4	+70.6	+ 4.4%	
FX effects <sup>1</sup>				-3.9pp	
Divestitures <sup>2</sup>				+6.3pp	
Regional portfolio				+4.6pp	
Japan diabetes portfolio				+1.0pp	
TACHOSIL				+0.5pp	
Others				+0.2pp	
Underlying Revenue Growth				+ 6.8%	

- 1. FX adjustment applies plan rate to both periods.
- 2. Major adjustments are as follow;
- Revenue of select over-the-counter and non-core products in Asia Pacific is excluded from FY2020 H1 as the divestiture was completed in November 2020.
- Revenue of select non-core prescription pharmaceutical products predominantly in Europe is excluded from FY2020 H1 as the divestiture was completed in December 2020.
- Revenue of select over-the-counter and non-core products in Latin America is excluded from FY2020 H1 as the divestiture was completed in January 2021.
- Net sales from TACHOSIL, a surgical patch, are excluded from FY2020 H1 as the divestiture was completed in January 2021.
- Revenue of select over-the-counter and non-core products predominantly in Europe is excluded from FY2020 H1 as the divestiture was completed in March 2021.
- Revenue of the former subsidiary, Takeda Consumer Healthcare Company Limited is excluded from FY2020 H1 as the divestiture was completed in March 2021.
- Net sales from a portfolio of diabetes products in Japan (NESINA, LIOVEL, INISYNC and ZAFATEK) are excluded from FY2020 H1 as the divestiture was completed at the beginning of April 2021. In addition, the non-recurring item of the 133.0 billion JPY selling price as the result of the completion of the divestiture is excluded from FY2021 H1.
- Revenue of select non-core prescription pharmaceutical products in China is excluded from both FY2021 H1 and FY2020 H1 as the divestiture was publicly announced and had been expected to complete within FY2021 H1. It is now expected to complete in FY2021 H2.

# RECONCILIATION FROM REPORTED REVENUE TO CORE/UNDERLYING REVENUE FY2021 Q2 (Jul-Sep) VERSUS PRIOR YEAR



(BN JPY)	FY2020 Q2 (Jul-Sep)	FY2021 Q2 (Jul-Sep)	vs. PY		
Reported Revenue	788.9	844.8	+55.9	+ 7.1%	
Sale of Japan diabetes portfolio <sup>2</sup>					
Core Revenue	788.9	844.8	+55.9	+ 7.1%	
FX effects <sup>1</sup>				-4.0pp	
Divestitures <sup>2</sup>				+6.8pp	
Regional portfolio				+5.0pp	
Japan diabetes portfolio				+1.0pp	
TACHOSIL				+0.6pp	
Others				+0.2pp	
Underlying Revenue Growth				+ 9.9%	

- 1. FX adjustment applies plan rate to both periods.
- 2. Major adjustments are as follow;
- Revenue of select over-the-counter and non-core products in Asia Pacific is excluded from FY2020 Q2 as the divestiture was completed in November 2020.
- Revenue of select non-core prescription pharmaceutical products predominantly in Europe is excluded from FY2020 Q2 as the divestiture was completed in December 2020.
- Revenue of select over-the-counter and non-core products in Latin America is excluded from FY2020 Q2 as the divestiture was completed in January 2021.
- Net sales from TACHOSIL, a surgical patch, are excluded from FY2020 Q2 as the divestiture was completed in January 2021.
- Revenue of select over-the-counter and non-core products predominantly in Europe is excluded from FY2020 Q2 as the divestiture was completed in March 2021.
- Revenue of the former subsidiary, Takeda Consumer Healthcare Company Limited is excluded from FY2020 Q2 as the divestiture was completed in March 2021.
- Net sales from a portfolio of diabetes products in Japan (NESINA, LIOVEL, INISYNC and ZAFATEK) are excluded from FY2020 Q2 as the divestiture was completed at the beginning of April 2021. In addition, the non-recurring item of the 133.0 billion JPY selling price as the result of the completion of the divestiture is excluded from FY2021 Q1.
- Revenue of select non-core prescription pharmaceutical products in China is excluded from both FY2021 Q2 and FY2020 Q2 as the divestiture was publicly announced and had been expected to complete within FY2021 H1. It is now expected to complete in FY2021 H2.

# RECONCILIATION FROM REPORTED TO CORE/UNDERLYING CORE FY2021 H1



(BN JPY)		REPORTED TO CORE ADJUSTMENTS							CORE TO UNDERLYING CORE ADJ.		
	REPORTED	Amortization of intangible assets	Impairment of intangible assets	Other operating income/ expense	Sale of Japan diabetes portfolio	Irish Tax Assessment <sup>1</sup>	Others	CORE	FX	Divestitures	UNDERLYING GROWTH
Revenue	1,794.4				-133.0			1,661.4	-64.8	-8.9	+6.8 %
Cost of sales	-517.1				0.6		22.3	-494.1	21.8	2.6	
Gross Profit	1,277.4				-132.4		22.3	1,167.2	-43.0	-6.2	
SG&A expenses	-431.9				1.0		2.1	-428.7	17.0		
R&D expenses	-254.1						1.3	-252.8	8.7		
Amortization of intangible assets	-204.1	204.1						_			
Impairment losses on intangible assets	-1.5		1.5					_			
Other operating income	19.5			-18.8			-0.7	_			
Other operating expenses	-59.4			59.4				_			
Operating profit	346.0	204.1	1.5	40.6	-131.4		25.0	485.7	-17.2	-6.2	+6.4 %
Margin	19.3 %							29.2%			29.1% <sup>2</sup>
Financial income/expenses	-58.0						-0.4	-58.5	5.2		
Equity income/loss	-3.5						6.4	2.8	0.1		
Profit before tax	284.4	204.1	1.5	40.6	-131.4		31.0	430.1	-11.9	-6.2	
Tax expenses	-100.7	-45.5	-0.5	-11.5	40.2	63.7	-39.9	-94.2	2.5	1.9	
Non-controlling interests	-0.1							-0.1	_		
Net profit	183.6	158.6	0.9	29.2	-91.2	63.7	-9.0	335.9	-9.4	-4.3	
EPS (yen)	117							214	-5	-3	+9.1 %
Number of shares (millions)	1,568						_	1,568			1,563

<sup>1.</sup> Tax charges of 63.7 billion JPY arising from the tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014, net of 0.5 billion JPY of associated tax benefit.

<sup>2.</sup> Underlying Core Operating Profit Margin.

# RECONCILIATION FROM REPORTED TO CORE/UNDERLYING CORE FY2021 Q2 (Jul-Sep)



(BN JPY)			REPORTED TO CORE ADJUSTMENTS							CORE TO UNDERLYING CORE ADJ.	
	REPORTED	Amortization of intangible assets	Impairment of intangible assets	Other operating income/ expense	Sale of Japan diabetes portfolio	Irish Tax Assessment <sup>1</sup>	Others	CORE	FX	Divestitures	UNDERLYING GROWTH
Revenue	844.8							844.8	-33.3	-4.6	+9.9 %
Cost of sales	-275.8						9.5	-266.3	11.2	1.2	
Gross Profit	569.0						9.5	578.5	-22.1	-3.4	
SG&A expenses	-212.0						1.2	-210.8	8.3		
R&D expenses	-131.6						0.6	-131.0	4.7		
Amortization of intangible assets	-101.3	101.3						_			
Impairment losses on intangible assets	-1.5		1.5					_			
Other operating income	8.4			-8.1			-0.4	_			
Other operating expenses	-33.7			34.4			-0.7	_			
Operating profit	97.4	101.3	1.5	26.3			10.3	236.8	-9.1	-3.4	+17.0 %
Margin	11.5 %							28.0 %			27.8 % <sup>2</sup>
Financial income/expenses	-32.8						2.1	-30.7	3.9		
Equity income/loss	-3.2						4.0	0.9			
Profit before tax	61.4	101.3	1.5	26.3			16.4	206.9	-5.2	-3.4	
Tax expenses	-15.5	-22.6	-0.5	-6.7		1.0	-3.4	-47.6	1.1	1.0	
Non-controlling interests	-0.0							-0.0	-0.0		
Net profit	46.0	78.7	0.9	19.6		1.0	13.0	159.3	-4.1	-2.4	
EPS (yen)	29							101	-2	-2	+15.4 %
Number of shares (millions)	1,572							1,572			1,563

<sup>1.</sup> Interest on tax charges arising from the tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014.

<sup>2.</sup> Underlying Core Operating Profit Margin.

# RECONCILIATION FROM REPORTED TO CORE/UNDERLYING CORE FY2020 H1



			REPORTE	D TO CORE ADJUS	STMENTS			CORE TO UNDERLYING CORE ADJ.		
(BN JPY)	REPORTED	Amortization of intangible assets	Impairment of intangible assets	Other operating income/ expense	TEVA JV related accounting adjustments	Others	CORE	FX	Divestitures	UNDERLYING GROWTH
Revenue	1,590.8						1,590.8	-2.6	-102.2	+0.5%
Cost of sales	-487.7					47.3	-440.4	-7.7	28.5	
Gross Profit	1,103.1					47.3	1,150.4	-10.4	-73.7	
SG&A expenses	-418.6			0.0		-0.6	-419.2	2.0	7.8	
R&D expenses	-225.0			-0.2		1.6	-223.6	0.9	0.4	
Amortization of intangible assets	-206.0	206.0					_			
Impairment losses on intangible assets	-2.1		2.1				_			
Other operating income	69.5			-8.6	-0.7	-60.2	_			
Other operating expenses	-105.2			86.7		18.6	_			
Operating profit	215.6	206.0	2.1	78.0	-0.7	6.7	507.6	-7.4	-65.5	+1.9%
Margin	13.6%						31.9%			29.3 % <sup>2</sup>
Financial income/expenses	-81.1					17.2	-63.9	3.5	-0.0	
Equity income/loss	-8.9				11.0		2.1	-0.0		
Profit before tax	125.6	206.0	2.1	78.0	10.3	23.9	445.8	-3.9	-65.5	
Tax expenses	-39.0	-42.2	-0.3	-13.5	-3.2	-2.1	-100.2	0.9	18.3	
Non-controlling interests	-0.0						-0.0	-0.0	0.0	
Net profit	86.5	163.8	1.8	64.5	7.2	21.8	345.5	-3.1	-47.2	
EPS (yen)	55						221	-2	-30	-0.4%
Number of shares (millions)	1,561						1,561			1,558

<sup>1.</sup> Underlying Core Operating Profit Margin.

# RECONCILIATION FROM REPORTED TO CORE/UNDERLYING CORE FY2020 Q2 (Jul-Sep)



(BN JPY)			REPORTE	D TO CORE ADJUS		CORE TO UNDERLYING CORE ADJ.				
	REPORTED	Amortization of intangible assets	Impairment of intangible assets	Other operating income/ expense	TEVA JV related accounting adjustments	Others	CORE	FX	Divestitures	UNDERLYING GROWTH
Revenue	788.9						788.9	-2.0	-52.8	+0.1%
Cost of sales	-249.6					20.7	-228.9	-1.2	14.9	
Gross Profit	539.3					20.7	560.0	-3.2	-37.9	
SG&A expenses	-216.3			0.0		-0.3	-216.6	1.6	4.2	
R&D expenses	-118.2			-0.1		1.5	-116.7	0.1	0.2	
Amortization of intangible assets	-103.6	103.6					_			
Impairment losses on intangible assets	-0.2		0.2				_			
Other operating income	5.7			-5.4	-0.4		_			
Other operating expenses	-58.5			58.5			_			
Operating profit	48.3	103.6	0.2	53.0	-0.4	21.9	226.7	-1.6	-33.4	-7.7%
Margin	6.1%						28.7%			26.1 %¹
Financial income/expenses	-53.9					18.3	-35.6	3.9		
Equity income/loss	0.8				0.5		1.3	-0.0		
Profit before tax	-4.7	103.6	0.2	53.0	0.1	40.2	192.4	2.3	-33.4	
Tax expenses	8.8	-22.5	-0.0	-10.8	-0.0	-12.9	-37.5	-0.7	9.3	
Non-controlling interests	-0.0						-0.0	0.0	0.0	
Net profit	4.0	81.1	0.2	42.2	0.1	27.3	154.9	1.6	-24.1	
EPS (yen)	3						99	1	-15	-9.6%
Number of shares (millions)	1,563						1,563			1,558

<sup>1.</sup> Underlying Core Operating Profit Margin.

## **FREE CASH FLOW**



(BN JPY)	FY2020 H1	FY2021 H1	vs. PY		
Net profit	86.6	183.7	+97.1	+112.2%	
Depreciation, amortization and impairment loss	288.8	285.1	-3.8		
Decrease (increase) in trade working capital	-24.9	-89.2	-64.3		
Income taxes paid	-103.8	-78.7	+25.1		
Tax refunds and interest on tax refunds received	23.7	4.8	-18.8		
Other	121.6	94.3	-27.3		
Net cash from operating activities	392.0	400.0	+8.0	+2.0%	
Adjustment for deposits restricted to certain vaccines operations	_	-7.6	-7.6		
Acquisition of PP&E	-50.5	-60.6	-10.1		
Proceeds from sales of PP&E	38.5	0.4	-38.1		
Acquisition of intangible assets	-30.4	-25.2	+5.2		
Acquisition of investments	-6.2	-3.6	+2.6		
Proceeds from sales and redemption of investments	50.6	10.1	-40.6		
Proceeds from sales of business, net of cash and cash equivalents divested	31.4	2.1	-29.3		
Free Cash Flow	425.5	315.6	-109.9	-25.8%	

## **NET DEBT/ADJUSTED EBITDA**



#### **NET DEBT/ADJUSTED EBITDA RATIO**

(BN JPY)	FY2021 H1				
Cash and cash equivalents <sup>1</sup>	424.8				
Book value debt on the balance sheet	-4,231.4				
Hybrid bond 50% equity credit	250.0				
FX adjustment <sup>2</sup>	107.3				
Gross debt <sup>3</sup>	-3,874.1				
Net cash (debt)	-3,449.3				
Net debt/Adjusted EBITDA ratio	3.1 x				
Adjusted EBITDA	1,112.2				

#### **NET INCREASE (DECREASE) IN CASH**

(BN JPY)	FY2020 H1	FY2021 H1	vs.	PY
Net cash from operating activities	392.0	400.0	+8.0	+2.0 %
Acquisition of PP&E	-50.5	-60.6		
Proceeds from sales of PP&E	38.5	0.4		
Acquisition of intangible assets	-30.4	-25.2		
Acquisition of investments	-6.2	-3.6		
Proceeds from sales and redemption of investments	50.6	10.1		
Acquisition of business, net of cash and cash equivalents acquired	_	-27.5		
Proceeds from sales of business, net of cash and cash equivalents divested	31.4	2.1		
Net increase (decrease) in short-term loans and commercial papers	-89.9	-0.0		
Repayment of long-term loans	-792.5	-220.1		
Proceeds from issuance of bonds	1,179.5	_		
Repayment of bonds	-473.1	-220.9		
Interest paid	-47.6	-52.7		
Dividends paid	-141.8	-141.6		
Others	-58.1	-22.1		
Net increase (decrease) in cash	2.0	-361.7	-363.8	_

<sup>1.</sup> Includes short-term investments which mature or become due within one year from the reporting date and excludes deposits restricted to certain vaccines operations.

<sup>2.</sup> FX adjustment refers to change from month-end rate to average rate used for non-JPY debt calculation outstanding at the beginning of the period to match with adjusted EBITDA (which is calculated based on average rates). New non-JPY debt incurred and existing non-JPY debt redeemed during the reporting period are translated to JPY at relevant spot rates as of the relevant date.

<sup>3.</sup> Bonds and loans of current and non-current liabilities. 250Bn yen reduction in debt due to 500Bn yen hybrid bond issuance in June 2019, given that the hybrid bond qualifies for 50% equity credit for leverage purposes. Includes cash and non cash adjustments to debt book-value. Non cash adjustments include changes dues to debt amortization and FX impact.

## NET PROFIT TO ADJUSTED EBITDA BRIDGE FY2021 H1 VERSUS PRIOR YEAR



(BN JPY)	FY2020 H1	FY2021 H1	vs. P	Y
Net profit	86.6	183.7	+97.1	+112.2%
Income tax expenses	39.0	100.7		
Depreciation and amortization	280.5	283.6		
Interest expense, net	68.2	58.9		
EBITDA	474.3	627.0	+152.7	+32.2%
Impairment losses	8.3	1.5		
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	27.5	36.8		
Finance expense (income), net, excluding interest income and expense, net	12.9	-0.9		
Share of loss on investments accounted for under the equity method	8.9	3.5		
Other adjustments:	65.1	-72.9		
Non-core expense related to COVID-19	_	5.5		
Sale of Japan diabetes portfolio	_	-131.4		
Impact on profit related to fair value step up of inventory in Shire acquisition	46.6	17.8		
Acquisition costs related to Shire	0.0	_		
Other costs <sup>1</sup>	18.5	35.2		
Adjusted EBITDA	597.1	595.0	-2.1	-0.4%

<sup>1.</sup> Includes adjustments for non-cash equity-based compensation expense and non-recurring wind-down costs related to pipeline de-prioritization after Shire acquisition.

### **NET PROFIT TO ADJUSTED EBITDA LTM BRIDGE**



(BN JPY)	FY2020 Full Year (Apr-Mar)	FY2020 H1	FY2021 H1	FY2021 H1 LTM <sup>1</sup> (Oct-Sep)
Net profit	376.2	86.6	183.7	473.3
Income tax expenses	-9.9	39.0	100.7	51.8
Depreciation and amortization	559.7	280.5	283.6	562.7
Interest expense, net	129.0	68.2	58.9	119.8
EBITDA	1,054.9	474.3	627.0	1,207.6
Impairment losses	25.5	8.3	1.5	18.6
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	-74.5	27.5	36.8	-65.2
Finance expense (income), net, excluding interest income and expense, net	14.1	12.9	-0.9	0.2
Share of loss on investments accounted for under the equity method	-0.1	8.9	3.5	-5.5
Other adjustments:	131.4	65.1	-72.9	-6.6
Non-core expense related to COVID-19	14.0	_	5.5	19.5
Sale of Japan diabetes portfolio	_	_	-131.4	-131.4
Impact on profit related to fair value step up of inventory in Shire acquisition	79.4	46.6	17.8	50.6
Acquisition costs related to Shire	1.9	0.0	_	1.9
Other costs <sup>2</sup>	36.1	18.5	35.2	52.8
Adjusted EBITDA	1,151.3	597.1	595.0	1,149.2
EBITDA from divested products <sup>3</sup>				-37.0
Adjusted EBITDA (LTM)				1,112.2

<sup>1.</sup> LTM represents Last Twelve Months (October 2020 - September 2021). Calculated by subtracting FY2020 H1 from FY2020 Full Year and adding FY2021 H1.

<sup>2.</sup> Includes adjustments for non-cash equity-based compensation expense and non-recurring wind-down costs related to pipeline de-prioritization after Shire acquisition.

<sup>3.</sup> Represents adjustments for EBITDA from divested products which are removed as part of LTM Adjusted EBITDA.

## **FY2021 DETAILED FORECAST**



(BN JPY)	FY2021 FY2021 Original Revised Forecast Forecast (May 11, 2021) (Oct 28, 2021)		vs. Original Forecast		Variances		
Revenue	3,370.0	3,370.0					
Cost of sales	N/D¹	N/D¹					
R&D expenses	-522.0	-522.0					
Amortization of intangible assets	-406.0	-406.0					
Impairment of intangible assets	-50.0	-50.0					
Other operating income	23.0	23.0					
Other operating income Other operating expenses Operating profit	-100.0	-100.0					
Operating profit	488.0	488.0					
Finance income/expenses	-130.0	-130.0					
Profit before tax	352.0	352.0					
Net profit	250.0	184.3	-65.7	-26.3%	Reflecting an estimated full year impact of a tax charge arising from a tax assessment involving Irish taxation, including interest		
EPS (yen)	160	117	-43	-26.6%	expected to be accrued through March 31, 2022.		
Core Operating Profit <sup>2</sup>	930.0	930.0					
Core EPS (yen)	394	394					
USD/JPY (yen)	108	108					
EUR/JPY (yen)	131	131					

<sup>1.</sup> Not Disclosed.

<sup>2.</sup> Please refer to slide 58 for reconciliation.

# FY2021 CORE OPERATING PROFIT ADJUSTMENT ITEMS & CASH FLOW FORECAST VERSUS ACTUALS



#### **CORE OPERATING PROFIT ADJUSTMENT ITEMS**

(BN JPY)	FY2021 H1	FY2021 Forecast (October 28, 2021)
Amortization of intangible assets	204.1	406.0
Of which Shire-acquisition related	166.3	328.0
Impairment of intangible assets	1.5	50.0
Other operating income	-18.8	-23.0
Other operating expenses	59.4	100.0
Japan diabetes portfolio divestiture gain - net of revenue and expenses	-131.4	-130.0
Other Core Operating Profit adjustments	25.0	39.0
Of which Shire-acquisition related to unwind of inventories step-up	17.8	31.1
Total core operating profit adjustments	139.8	442.0

#### **CASH FLOW GUIDANCE**

(BN JPY)	FY2021 H1	FY2021 Forecast (October 28, 2021)
Free cash flow (including announced divestitures)	315.6	600.0 to 700.0
CAPEX (cash flow base)	-85.8	-210.0 to -260
Depreciation and amortization (excluding intangible assets associated with products)	-77.8	-150.0
Cash tax rate on adjusted EBITDA (excluding divestitures)	N/A	mid-teen %

# RECONCILIATION FROM REPORTED OPERATING PROFIT TO CORE OPERATING PROFIT – FY2021 FORECAST



(BN JPY)	REPORTED	Amortization of intangible assets	Impairment of intangible assets	Other operating income/ expenses	Sale of Japan diabetes portfolio	Others	CORE
Revenue	3,370.0				-133.0		3,237.0
Cost of sales					3.0	35.0	
Gross Profit					-130.0	35.0	
SG&A and R&D expenses						4.0	
Amortization of intangible assets	-406.0	406.0					_
Impairment losses on intangible assets	-50.0		50.0				_
Other operating income	23.0			-23.0			_
Other operating expenses	-100.0			100.0			_
Operating profit	488.0	406.0	50.0	77.0	-130.0	39.0	930.0

## **FX RATES AND FY2021 CURRENCY SENSITIVITY**



### **Average Exchange Rates vs. JPY**

## Impact of 1% depreciation of yen from April 2021 to March 2022 (100 million JPY) based on FY2021 forecast

				(100 million JFT) based on FT2021 forecast					
	FY2020 Actual (Apr-Sep)	FY2021 Actual (Apr-Sep)	FY2021 Assumption (Apr-Mar)	Revenue (IFRS)	Operating Profit (IFRS)	Net Profit (IFRS)	Core Operating Profit (non-IFRS)		
USD	107	110	108	+170.7	+29.4	+16.7	+69.2		
EUR	121	131	131	+45.0	-31.4	-27.0	-19.5		
RUB	1.5	1.5	1.4	+3.7	+2.1	+1.7	+2.5		
CNY	15.2	17.0	16.8	+10.7	+5.9	+4.4	+6.0		
BRL	20.1	20.9	19.9	+5.8	+3.7	+2.5	+3.8		

### MAXIMIZING THE VALUE OF OUR GLOBAL AND REGIONAL BRANDS



**PHASE 1 & 2** PHASE 3 **FILED** 



**NINLARO®** 

Proteasome inhibitor Maint. ND MM post-SCT (US, EU)

NINLARO<sup>®</sup>

Proteasome inhibitor Maint. ND MM no SCT (US, EU, CN)

**ICLUSIG**<sup>®</sup>

BCR-ABL inhibitor FL Ph+ ALL (US)

**ALUNBRIG**®

ALK inhibitor 2L ALK+NSCLC H2H with alectinib (GL)

**CABOMETYX®** 

VEGFR/RTK inhibitor mCRPC combo w/atezolizumab (JP)

**CABOMETYX®** 

VEGFR/RTK inhibitor 2L mNSCLC combo w/atezolizumab (JP)

**ALUNBRIG®** ALK inhibitor 1L & 2L ALK+NSCLC (CN)

> • 🕢 NINLARO®

Proteasome inhibitor Maint, ND MM no SCT (JP)

• 🕔 **ADCETRIS®** Seagen CD30 ADC

> CTCL (CN) V

**CABOMETYX®** VEGFR/RTK inhibitor 1L RCC combo w/nivolumab (JP)



NATPARA<sup>®</sup>

PTH replacement Hypothyrodism (JP) **TAKHZYRO**<sup>®</sup>

Anti-kallikrein mAb HAE pediatric (GL)

**TAKHZYRO®** 

Anti-kallikrein mAb BMA (GL)

**VONVENDI®** 

vWF replacement vWD Pediatric on-demand & surgery (GL)

**ADYNOVATE®** 

recombinant Factor VIII Pediatric HemA (EU)

**TAKHZYRO®** 

Anti-kallikrein mAb HAE (JP)

**VONVENDI®** 

vWF replacement vWD Adult Prophylaxis (GL)



ENTYVIO<sup>®</sup>

α4β7 mAb Pediatric UC/CD (GL) **ENTYVIO®** 

α4β7 mAb SubQ CD (US, JP)

**ENTYVIO®** 

α4β7 mAb GvHD Prophylaxis (EU, JP) **VOCINTI®** 

**PCAB** H. Pylori (CN)

**ALOFISEL®** 

mesenchymal stem cells Perianal Fistulas in CD (US)

**ENTYVIO®** 

α4β7 mAb SubQ UC (US, JP)

**ENTYVIO®** 

α4β7 mAb

**VOCINTI®** 

PCAB Reflux Esophagitis Maintenance (CN)

formulation (JP)

Antibiotic-refractory Oral disintegrated tablet Pouchitis (EU)

V

**GATTEX®** GLP-2R agonist

Pediatric-SBS (JP) • 🕢

• 🕢

**ALOFISEL®** mesenchymal stem cells Perianal Fistulas in CD (JP)

• 🕢



PDT

**CEPROTIN®** Protein C Concentrate SCPCD (JP)

**CUVITRU®** 

IgG 20% (human) subcutaneous PID (JP)

**HYQVIA**<sup>®</sup>

Halozyme IgG 10% + Recombinant Human Hyaluronidase CIDP (US, EU)

HYQVIA<sup>®</sup>

Halozyme IgG 10% + Recombinant Human Hyaluronidase Pediatric PID (US)

**HYQVIA**°

Halozyme IgG 10% + Recombinant Human Hyaluronidase HyHub Device (US)

**TAKECAB®** PCAB

**GATTEX**<sup>®</sup> GLP-2R agonist Adult-SBS (JP)

Orphan Drug Designation (in any region / indication for a given asset)



Approved since Q4 FY20

## **CONTINUED GLOBAL AND REGIONAL BRAND EXPANSION IN FY2021**



	COMPOUND	EXPECTED EVENT <sup>1</sup>	FY21	L	Comments
- 0	ADCETRIS	Approval decision for CTCL in China	H1	<b>✓</b>	
ONCOLOGY	NINLARO	Approval decision in JP for maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant	H1	<b>✓</b>	
	ICLUSIG	Submission in US for front line Ph+ Acute Lymphoblastic Leukemia	H2	<b>→</b>	Submission expected in FY22, based on upcoming final analysis
RARE GENETICS & HEMATOLOGY	TAKHZYRO	Approval decision in JP for hereditary angioedema	H2		
	FIRAZYR	Approval decision for hereditary angioedema in China	Н1	<b>✓</b>	
	VONVENDI	Approval decision in US for prophylaxis therapy in Von Willebrand Disease	H2		
	GATTEX/ REVESTIVE	Approval decision in JP for short bowel syndrome	H1	<b>✓</b>	
	ALOFISEL	Approval decision in JP for refractory complex perianal fistulas in patients with Crohn's disease	H2	<b>✓</b>	
GASTRO-	ENTYVIO	Pivotal study start in needle-free jet injector	H2		
ENTEROLOGY	TAKECAB/	Approval decision in JP for oral disintegrated tablet formulation	H2		
	VOCINTI	Approval decision for acid related diseases (Reflux Esophagitis Maintenance) in China	H2	<b>✓</b>	
CELLE	COVID-19 Vaccine Moderna IM	Approval decision in JP for prevention of COVID-19 (TAK-919)	H1	<b>✓</b>	
VACCINES	TAK-019	Approval decision in JP for prevention of COVID-19 (partner Novavax)	H2		

<sup>1.</sup> All timelines are approximate estimates as of October 28, 2021 and are subject to change. *Green tick mark indicates that milestone has been achieved.* Table only shows selected R&D milestones and is not comprehensive. For full glossary of disease abbreviations please refer to appendix.

### **R&D ENGINE DRIVING WAVE 1 APPROVALS AND EXPANSION OF GLOBAL AND REGIONAL BRANDS**



EXKIVITY		2L NSCLC EXON 20; US	EXKIVITY	2L NSCLC EXON 20; EU, CN	TAK-755	сТТР	TAK-994 <sup>3</sup>	Narcolepsy T1	
mobocertinib maribavir		R/R CMV Transplant	mobocertinib		EXKIVITY	1L NSCLC EXON 20	TAK-007	Hematological malignancies	
TAK-620		K/K CIVIV Transplant	TAK-003 idursulfase IT	Dengue vaccine	mobocertinib maribavir	al Chartenandon	arylsulfatase A TAK-611	MLD (IT)	
Eohilia <sup>1</sup> TAK-721	Ē	EoE	TAK-609	MPSII CNS	TAK-620	1L CMV Transplant	ENTYVIO SC	CD/UC Needle free; EU	
TAKHZYRO		нае; ЈР	ALUNBRIG	1L ALK+ NSCLC; CN 2L ALK+ NSCLC; CN	soticlestat TAK-935	DS LGS	GATTEX	SBS; CN	
NINLARO	~	NDMM nSCT; JP	ENTYVIO	AB-refract pouchitis; EU	ALOFISEL	CPF; US	NINLARO	NDMM nSCT; EM NDMM nSCT (CN); CN	
ALOFISEL	~	CPF; JP	HYQVIA	Pediatric PID; US	ALUNBRIG	H2H Alectinib NSCLC;	HYQVIA	PID, SID; JP	
GATTEX	~	SBS; JP		HyHub Device; EU, US		US,EU	Niraparib	CRPC; JP	
Vonvendi		VWD Prophy; US	Vonvendi	VWD Prophy; JP	ADYNOVATE	HemA; CN	vonoprazan	H.pylori; CN	
Aralast TAK-883		AADE ARA; EU	ICLUSIG	1L Ph+ ALL; EU,US	ENTYVIO SC	UC/CD SC; JP,US <sup>2</sup> CD/UC Needle free; US	TAK-880 Low	PID Low IgA; EU	
vonoprazan OD		ARD; JP			NINLARO	NDMM nSCT; EU,US NDMM SCT; EU,US	lgA relugolix	PC; CN	
vonoprazan	<b>×</b>	EE maint; CN				BMA; US		VWD Peds; EU,JP,US	
cabozantinib	<b>Y</b>	1L RCC; JP			TAKHZYRO	HAE Peds; EU,US	Vonvendi	VWD Prophy; EU	
ADCETRIS	<b>&gt;</b>	CTCL; CN				CIDP; EU,US	i		
TAK-919 TAK-019	~	COVID-19			HYQVIA	MMN; EU HyHub Duo Device; EU,US			
					Gammagard Liquid	CIDP; US	Ì		
					CUVITRU	PID, SID; JP	Ì		
					ADCETRIS	CTCL; JP			
					CEPROTIN	SCPCD; JP			
					TAK-880 Low IgA	PID Low IgA; US			
					cabozantinib	mCRPC; JP NSCLC; JP			
					Vonvendi	VWD; CN			
	<u> </u>			0					
F\	Y 2	1	E.	Y22	FY	) 3 )		FY24	

#### **Milestone: Potential approval**

- **Potential approval of New Molecular Entities**
- Potential extensions to global brands
- Potential extensions to regional brands
  - Achieved approvals

3. TAK-994 approval timelines under review

In active discussions with the FDA. Potential approval subject to outcome of discussions.
 In active discussions with the FDA. Timelines under review; potential approval anticipated FY23.

## **GLOSSARY OF ABBREVIATIONS**



#### **Regional Abbreviations:**

CN: China; EU: Europe; JP: Japan; US: United States of America

CIV. CIIIIIa,	Lo. Europe, 11 . Japan, 05. Officed States of Afficine
AATD	lpha1-antitrypsin deficiency
AD	Alzheimer's disease
ADC	antibody drug conjugate
ADHD	attention deficit hyperactivity disorder
AHA	acquired hemophilia A
ALK	anaplastic lymphoma kinase
ALCL	anaplastic large-cell lymphoma
AML	acute myeloid leukemia
ASCT	autologous stem cell transplant
ARD	acid-related diseases
AVA	Advanced Vial Access
BBB	blood brain barrier
BLA	biologics license application
вма	bradykinin mediated angioedema
BTD	breakthrough therapy designation
втк	Bruton's tyrosine kinase
BOS	budesonide oral suspension
CAR-T	chimeric antigen receptor-T
CD	Crohn's disease
CHAWI	congenital hemophilia A with inhibitors
CHMP	Committee for Medicinal Products for Human Use
CIAS	cognitive impairment associated with schizophrenia
CIDP	chronic inflammatory demyelinating polyradiculoneuropathy
CLL	chronic lymphocytic leukemia
CML	chronic myeloid leukemia
CMML	chronic myelomonocytic leukemia
CMV	cytomegalovirus
CSF	cerebrospinal fluid
CNS	central nervous system
CPF	complex perianal fistulas
CRL	complete response letter

CRPS	complex regional pain syndrome
CTCL	cutaneous T-cell lymphoma
сТТР	congenital thrombotic thrombocytopenic purpura
DAAO	D-amino acid oxidase
DEE	developmental and epileptic encephalopathies
DLBCL	diffuse large B-cell lymphoma
DS	Dravet syndrome
DU	duodenal ulcer
Dx	diagnosis
EDS	excessive daytime sleepiness
EE H	erosive esophagitis healing
EE M	erosive esophagitis maintenance
EFI	enteral feeding intolerance
EGFR	epidermal growth factor receptor
EMA	European Medicines Agency
EOE	eosinophilic esophagitis
ESCC	esophageal squamous-cell carcinoma
FDA	the U.S. Food & Drug Administration
FL	front line
FSI	first subject in
GCC	guanylyl cyclase C
GERD	gastroesophageal reflux disease
GI	gastrointestinal
GnRH	gonadotropin-releasing hormone
GU	gastric ulcer
GvHD	graft versus host disease
HAE	hereditary angioedema
H2H	head-to-head
нсс	hepatocellular carcinoma
HemA	hemophilia A
HER2	human epidermal growth factor receptor 2
HL	Hodgkin lymphoma
HR MDS	higher-risk myelodysplastic syndromes
HSCT	hematopoietic stem cell transplant
IBD	inflammatory bowel disease

IH	idiopathic hypersomnia
IND	investigational new drug
iNHL	Indolent non-Hodgkin's lymphoma
1/0	immuno-oncology
iTTP	immune thrombotic thrombocytopenic purpura
IV	intravenous
iPSC	induced pluripotent stem cells
L-ASA	low dose aspirin
LBD	Lewy body dementia
LB AML	low-blast acute myeloid leukemia
LSD	lysosomal storage disorder
LCM	lifecycle management
LGS	Lennox-Gastaut syndrome
mAb	monoclonal antibody
MAOB	monoamine oxidase B
MDD	major depressive disorder
MG	myasthenia gravis
MLD	metachromatic leukodystrophy
MM	multiple myeloma
NAE	NEDD8 activating enzyme
ND	newly diagnosed
NDA	new drug application
Neg	Negative
NERD	non-erosive reflux disease
NHL	non-Hodgkin's lymphoma
NK	natural killer
NME	new molecular entity
NMPA	National Medical Products Administration
NSCLC	non-small cell lung cancer
NSCT	non stem cell transplant
NS	negative symptoms
NT1 or 2	narcolepsy Type 1 or 2
ORR	overall response rate

OSA	obstructive sleep apnea
PARP	poly (ADP-ribose) polymerase
PAS	prior approval supplement
PBS	phosphate buffered saline
PCAB	potassium competitive acid blocker
Ph+ ALL	Philadelphia chromosome-positive acute lymphoblastic leukemia
PID	primary immunodeficiency
PK	pharmacokinetics
POC	proof of concept
POGD	post-operative gastrointestinal dysfunction
POI	post-operative ileus
PTCL	peripheral T-cell lymphoma
PTH	parathyroid hormone
R/R	relapsed/refractory
RCC	renal cell cancer
RTK	receptor tyrosine kinase
sALCL	systemic anaplastic large cell lymphoma
SBS	short bowel syndrome
sc	subcutaneous formulation
SCD	sickle cell disease
SCT	stem cell transplant
SCZ	schizophrenia
SID	secondary immunodeficiency
SLE	systemic lupus erythematosus
sq	squamous
STING	stimulator of interferon genes
SUMO	small ubiquitin-related modifier
TESD	treatment emergent sexual dysfunction
TKI	tyrosine kinase inhibitor
TRD	treatment resistNMPAant depression
UC	ulcerative colitis
vWD	von Willebrand disease

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