

### **TAKEDA R&D INVESTOR DAY 2019**



**NEW YORK, NY** 

November 14, 2019

Better Health, Brighter Future

# R&D DAY AGENDA – NEW YORK, NOVEMBER 14, 2019



TIME	AGENDA			
12:30 – 12:35	Welcome and Opening Remarks Sheelagh Cawley-Knopf, Head R&D Global Portfolio Strategy			
12:35 – 12:45	Takeda: A Global Values-Based, R&D-Driven Biopharmaceutical Leader Christophe Weber, President & CEO Takeda			
12:45 – 13:20	Translating Science into Highly Innovative, Life-changing Medicines  Andy Plump, President R&D			
13:20 – 13:45	Oncology and Cell Therapies with Spotlight on CAR-NK Chris Arendt, Head Oncology Drug Discovery Unit			
13:45 – 14:05	Spotlight on Oncology Opportunities • TAK-788 : Rachael Brake, Global Program Lead • Pevonedistat : Phil Rowlands, Head Oncology Therapeutic Area Unit			
14:05 – 14:20	Break			
14:20 – 14:45	Rare Diseases & Gene Therapy Dan Curran, Head Rare Disease Therapeutic Area Unit			
14:45 – 15:00	Spotlight on Orexin2R agonists Deborah Hartman, Global Program Lead			
15:00 – 15:20	Therapeutic Area Focus in GI with Spotlight on Celiac Disease Asit Parikh, Head GI Therapeutic Area Unit			
15:20 – 16:00	Panel Q&A Session			
16:00	Drinks reception			

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The companies in which Takeda directly and indirectly owns investments are separate entities. In this presentation, "Takeda" is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words "we", "us" and "our" are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

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#### Medical information

This presentation contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

#### Einancial informatio

Takeda's financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS").

The revenue of Shire plc ("Shire"), which were presently, presented in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"), have been conformed to IFRS, without material difference.

The Shire acquisition closed on January 8, 2019, and our consolidated results for the fiscal year ended March 31, 2019 include Shire's results from January 8, 2019 to March 31, 2019. References to "Legacy Takeda" businesses are to our businesses held prior to our acquisition of Shire. References to "Legacy Shire" businesses are to those businesses acquired through the Shire acquisition.

This presentation includes certain pro forma information giving effect to the Shire acquisition as if it had occurred on April 1, 2018. This pro forma information has not been prepared in accordance with Article 11 of Regulation S-X. This pro forma information is presented for illustrative purposes and is based on certain assumptions and judgments based on information available to us as of the date hereof, which may not necessarily have been applicable if the Shire acquisition had actually happened as of April 1, 2018. Moreover, this pro forma information gives effect to certain transactions and other events which are not directly attributable to the Shire acquisition and/or which happened as ubsequently to the Shire acquisition, such as divestitures and divestitures and the effects of the purchase price allocation for the Shire acquisition, and therefore may not accurately reflect the effect on our financial condition and results of operations if the Shire acquisition had actually been completed on April 1, 2018. Therefore, undue reliance should not be placed on the pro forma information included herein.

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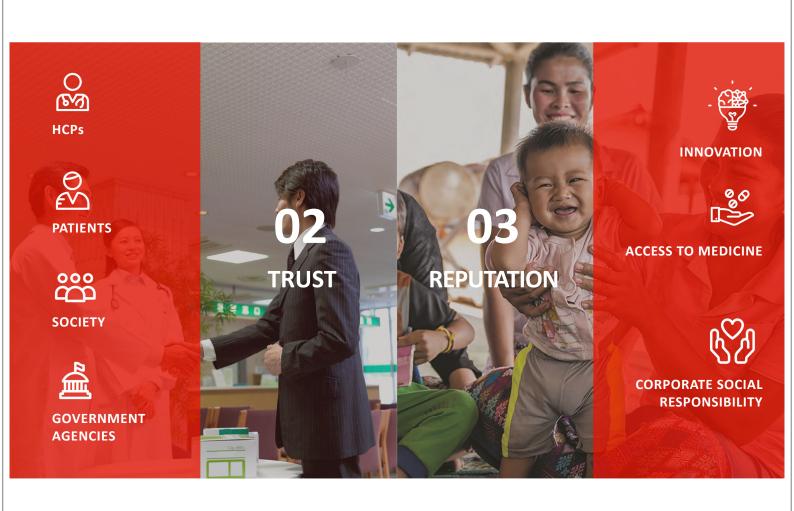


# **TAKEDA-ISM**

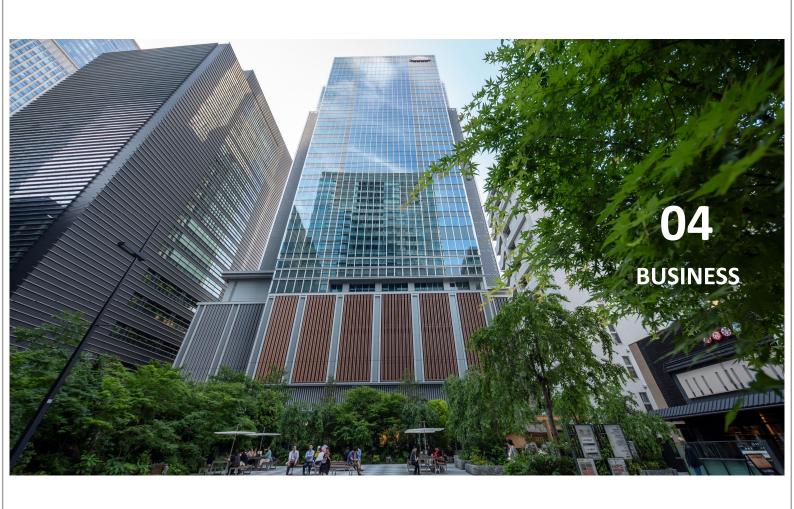








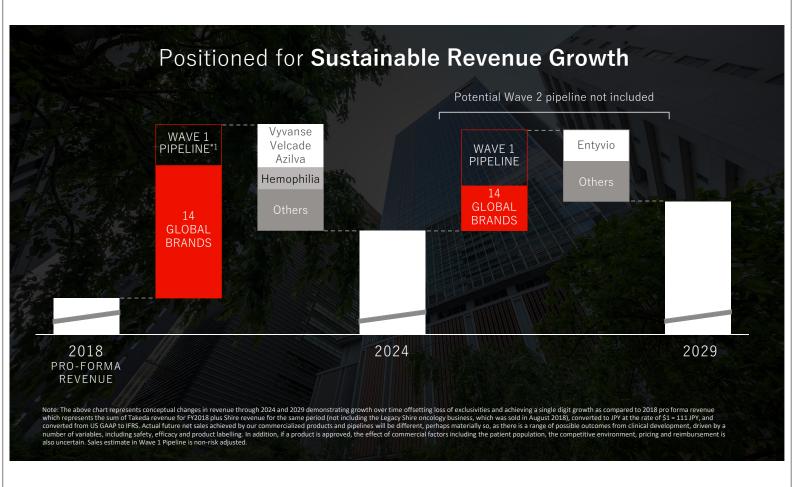






SCIENCE DRIVEN COMPANY WITH A FOCUSED MIND







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# TRANSLATING SCIENCE INTO HIGHLY INNOVATIVE LIFE-CHANGING MEDICINES



Andy Plump MD, PhD

President R&D
Takeda Pharmaceutical Company Limited
New York, NY
November 14, 2019

Better Health, Brighter Future

### WHAT YOU WILL HEAR TODAY



1

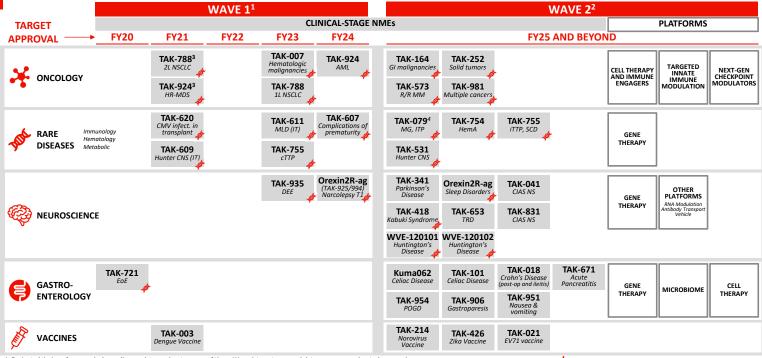
Our portfolio and pipeline will drive growth and offset key patent expirations 2

We are investing in novel mechanisms and capabilities for a sustainable future 3

We have cultivated an environment of empowerment, accountability and agility

# WE ARE POSITIONED TO DELIVER NEAR-TERM & SUSTAINED GROWTH Takeda





- Projected timing of approvals depending on data read-outs; some of these Wave 1 target approval dates assume accelerated approval
   Some Wave 2 assets could be accelerated into Wave 1 if they have breakthrough data
   Projected approval date assumes filing on Phase 2 data
- 4. TAK-079 to be developed in Rare Diseases indications myasthenia gravis (MG) and immune thrombocytopenic purpura (ITP) (FPI projected in each indication in 2H FY19)

Orphan potential in at least one indication Estimated dates as of November 14, 2019

### 2019: A WATERSHED YEAR FOR TAKEDA





- 18 assets added to the clinical pipeline\*
- Creation of a Rare Diseases Therapeutic Area
- Access to world-class Gene Therapy capabilities
- VARSITY study demonstrated head-to-head superiority of Entyvio vs Humira and published in New England Journal of Medicine
- TAKHZYRO indication expansions in bradykinin mediated angioedema
- · Expecting >15 approvals in China over the next 5 years
- 17 NMEs in Phase 2 and Phase 3
- · Potentially curative novel mechanisms (e.g. TAK-101, Orexin2R-ag, CAR-NK)
- · Momentum in Cell Therapies, including new partnership with MD Anderson

<sup>\*</sup> Including approved products with ongoing R&D investment

### PATIENT-DRIVEN AND SCIENCE-FIRST IN 3 CORE AREAS



#### **INNOVATIVE BIOPHARMA**









#### **PLASMA DERIVED THERAPIES**



Complementing our rare disease focus

#### **VACCINES BUSINESS UNIT**



Differentiated Dengue vaccine

### WE ARE DOING MORE FOR OUR PATIENTS

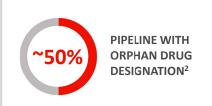














 $<sup>1.</sup> BIC/FIC Best-In-Class/First-In-Class (incl. relugolix). Three NMEs in pivotal studies in 2018 \\ 2. 31 Orphan Drug Designations in at least one indication for assets in Phase 1 through LCM in 2019 versus 15 in 2018 \\ 2. 32 Orphan Drug Designations in at least one indication for assets in Phase 1 through LCM in 2019 versus 15 in 2018 \\ 3. 32 Orphan Drug Designations in at least one indication for assets in Phase 2 through LCM in 2019 versus 15 in 2018 \\ 3. 32 Orphan Drug Designations in at least one indication for assets in Phase 2 through LCM in 2019 versus 15 in 2018 \\ 3. 32 Orphan Drug Designations in at least one indication for assets in Phase 2 through LCM in 2019 versus 15 in 2018 \\ 3. 32 Orphan Drug Designations in 2018 \\ 3. 32 Orphan Drug Designations in 2019 versus 2 through LCM in 2019 versus 2 through L$ 

# WE ARE TAKING COURAGEOUS RISKS TO MAKE A CRITICAL DIFFERENCE (Takeda)



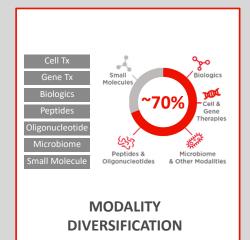
"There is a considerable need for improved treatments for individuals with NT1, which is caused by the loss of orexinproducing neurons in the brain"



Dr. Makoto Honda, Sleep Disorders Project Leader, Tokyo Metropolitan Institute of Medical Science

Data presented at World Sleep conference

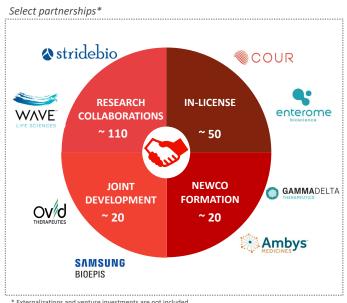
**NOVEL TARGET MECHANISMS WITH HUMAN VALIDATION** 

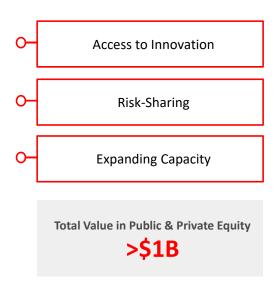


**Accelerated programs** NME stage-ups since FY18 Indications terminated or externalized since FY18 FAST GO / NO-GO **DECISION MAKING** 

#### WE ARE CULTIVATING THE BEST SCIENCE THROUGH **DIFFERENTIATED PARTNERSHIPS...**







<sup>\*</sup> Externalizations and venture investments are not included

# WE ARE NURTURING INNOVATION WHEREVER IT OCCURS





Representative examples only

### TO DRIVE HIGHER RETURN ON OUR \$4.5B ANNUAL R&D INVESTMENT (Takeda)





Minimize internal spend and infrastructure

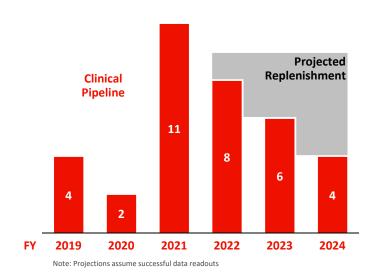
Smaller trials, lower costs, potential longer exclusivity

Success driven milestone payments

#### A RESEARCH ENGINE FUELING A SUSTAINABLE PIPELINE



#### POTENTIAL NME PIVOTAL STUDY STARTS BY YEAR



#### **IMPROVED PRODUCTIVITY**

- Research momentum building with a projected ~18 portfolio entries in FY19
- Productivity likely to increase with expansion of cell and gene therapy capabilities
- Leveraging partnerships to access the best clinical or preclinical innovation

### PIPELINE INVESTMENTS SUPPORTING NEAR-TERM GROWTH





### WE ARE DRIVING EXPANSION OF OUR GLOBAL BRANDS



#### **SELECT GLOBAL GROWTH BRANDS**

TAU Therapies		New Indications / Geographic Expansions	Target (FY)	
1L Non Small Cell Lung Canc		1L Non Small Cell Lung Cancer	2020	
ONC	NINLARO (kazomib) capsules	ND MM Maintenance (non-SCT and post-SCT)	2020 / 2022	
TOTAL	TAKHZYRO* (laradelumab-flyo) injection	Bradykinin Mediated Angioedema	2024	
Rare	vonvendi *	Prophylactic Treatment of von Willebrand Disease	2021	
_		Ulcerative Colitis, Crohn's Disease (subcutaneous formulation)	2019 / 2020	
		Graft versus Host Disease (prophylaxis)	2022	
GI	Λ L FIS ≣ L	Complex Perianal Fistulas	2021	

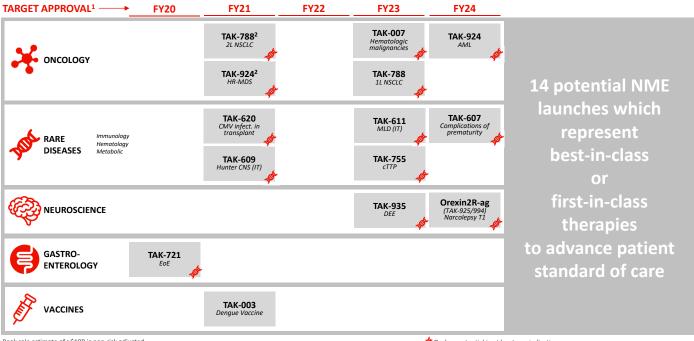
#### **SELECT REGIONAL EXPANSIONS**

Region	Therapies			Region	Therapies		
China	Entyvio vedolizumab ALUNBRI BRIGATINIB	TAKHZYRO (lanadelumab-flyo) injection	VPRIV velaglucerase alfa for injection	ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated]	Japan	Takecab*	relugolix, cabozantinib, niraparib

ND MM: newly diagnosed multiple myeloma SCT: stem cell transplant

#### WAVE 1 NEW MOLECULAR ENTITIES HAVE POTENTIAL TO DELIVER >\$10B AGGREGATE PEAK SALES...





Peak sale estimate of >\$10B is non-risk adjusted

- 1. Projected timing of approvals depending on data read-outs; some of these Wave 1 target approval dates assume accelerated approval 2. Projected approval date assumes filing on Phase 2 data

orphan potential in at least one indication

<sup>\*</sup> VONVENDI is emerging as a global brand Estimated dates as of November 14, 2019

# ...AND ARE EXPECTED TO DELIVER LIFE-CHANGING MEDICINES



POTE	NTIAL FIRS	T-IN-CLASS OR BES	ST-IN-CLASS NMEs				
		PRODUCT	MECHANISM	INDICATION	TARGET APPROVAL DATE (FY) <sup>1</sup>	ADDRESSABLE POPULATION (IN US) <sup>2</sup>	ADDRESSABLE POPULATION (WW) <sup>2,3</sup>
		● TAK-788	EGFR inhibitor (exon 20)	NSCLC – 2L / 1L	20214 / 2023	~2k	~20 - 30k
*	ONCOLOGY	pevonedistat (TAK-924)	NAE inhibitor	HR-MDS / AML	20214 / 2024	~7k / ~12k	15 - 20k / 20 - 25k
•		TAK-007	CD19 CAR-NK	Hematologic malignancies	2023	~9k	~15 - 25k
		● TAK-609	ERT / I2S replacement	Hunter CNS (IT)	2021	~250	~1 - 1.5k
A.	RARE	maribavir (TAK-620)	UL97 kinase inh	CMV infect. in transpl.	2021	~7 - 15k	~25 - 45k
700	DISEASES	TAK-607	IGF-1/ IGFBP3	Complications of prematurity	20245	~25k	~80 - 90k
	Immunology Hematology Metabolic	TAK-611	ERT / arylsulfatase A	MLD (IT)	2023	~350	~1 - 2k
		● TAK-755	ERT/ ADAMTS-13	cTTP / iTTP	2023 / 2025	~500 / ~2k	2 - 6k / 5 - 18k
æðs.		Orexin programs	Orexin 2R agonist	Narcolepsy Type 1	2024	70 - 140k	300k - 1.2M
ACCOUNTY.	NEUROSCIENCE	TAK-935	CH24H inhibitor	Developmental and Epileptic Encephalopathies (DEE)	2023	~50k	~70 - 90k
	GASTRO- ENTEROLOGY	● TAK-721	Oral anti-inflammatory	Eosinophilic Esophagitis	2020	~150k	Under evaluation
	VACCINES	• TAK-003	Vaccine	Dengue	2021	~32M	~1.8B

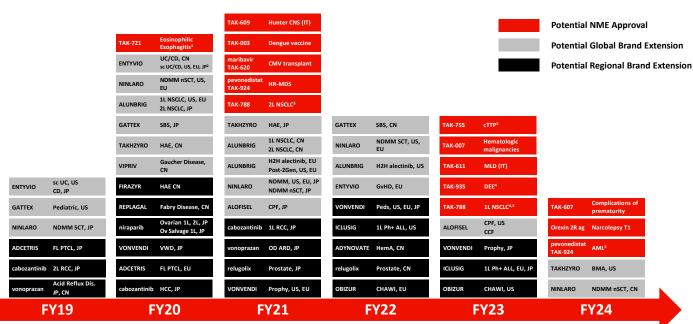
Projected timing of approvals depending on data read-outs; some of these target approval dates assume accelerated approval
 Estimated number of patients projected to be eligible for treatment in markets where the product is anticipated to be

commercialized, subject to regulatory approval 3. For TAK-788, TAK-924, TAK-007, TAK-607 and TAK-620 the addressable population represent annual incidence

- 4. Projected approval date assumes filing on Phase 2 data 5. Currently in a non-pivotal Ph 2; interim stage gates may advance program into pivotal trial for target approval by 2024
- Currently in pivotal study or potential for registration enabling Ph-2 study (note: table excludes relugolix)

### IN SUMMARY: ROBUST NEAR-TERM GROWTH





1. China approval in 2023 2. US approval for sc CD, EU approval for sc CD, Japan approval for sc CD

3. Includes approval in China

China approval in 2024
 New indication for currently unapproved asset

Potential approvals by fiscal year as of November 14, 2019 The target dates are estimates based on current data and subject to change

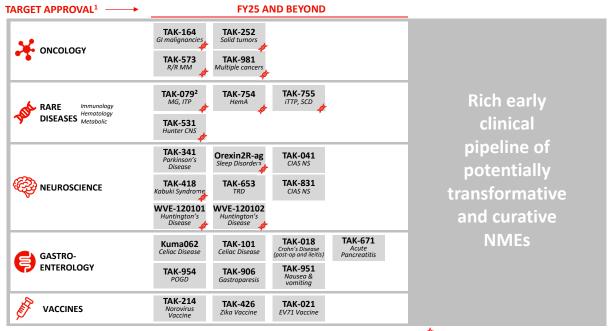
#### **SUSTAINED GROWTH BEYOND FY25**





### DRIVEN BY A CLINICAL PIPELINE OF NOVEL MECHANISMS...





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Orphan potential in at least one indication Estimated dates as of November 14, 2019

### ...AND WITH OUR NEXT-GENERATION PLATFORMS



#### **FY25 AND BEYOND** TARGET APPROVAL TARGETED INNATE IMMUNE MODULATION NEXT-GEN CHECKPOINT MODULATORS Attenukine Teva STING CuraDev, Takeda GammaDelta CAR-T GammaDelta Tx Conditional T cell engagers Maverick Agonist-redirected checkpoints Shattuck ONCOLOGY Humabodies Crescendo SUMOylation Takeda Harnessing the Immunology Hematology Metabolic **GENE THERAPY** DISEASES Hemophilia Lysosomal Storage Diseases potential of cell and gene therapies and OTHER PLATFORMS RNA Modulation Wave, Skyhawk Itibody Transport Vehicle other diverse **GENE THERAPY** NEUROSCIENCE modalities GENE THERAPY GASTRO-**CELL THERAPY** Liver Ambys **ENTEROLOGY**

Some Wave 2 assets could be accelerated into Wave 1 if they have breakthrough data

Estimated dates as of November 14, 2019

### **INVESTING IN CAPABILITIES TO POSITION US FOR SUCCESS**





#### **Cell Therapy**

- 5 clinical programs by end of FY20
- Disruptive platforms, including off-theshelf cell-therapies



#### **Gene Therapy**

- World-class gene therapy manufacturing
- Accessing innovation through partnerships (e.g. Stridebio, Ambys)



#### **Data Sciences**

- Accelerate clinical development with real world data (e.g. TAK-788)
- Use machine learning to identify rare disease patients



### **COMMITTED TO OUR PEOPLE**









### LIVING OUR VALUES THROUGHOUT THE INTEGRATION PROCESS





\* Where legally cleared

#### STRONG LEADERSHIP EXECUTING ON OUR VISION





ASIT PARIKH Therapeutic Area Unit



PHIL ROWLANDS Head, Oncology Therapeutic Area Unit



DAN CURRAN Head, Rare Diseases



EMILIANGELO RATTI Head, Neuroscience Therapeutic Area Unit



SARAH SHEIKH Head, Neuroscience Therapeutic Area Unit\*





\*Sarah Sheik to succeed Emiliangelo Ratti upon his retirement beginning November 25

<sup>†</sup>includes Regulatory, Global Patient Safety Evaluation, Development Operations, and Clinical Supply Chain



STEVE HITCHCOCK Head, Research



NENAD GRMUSA Head, Center for External Innovation



GEORGIA KERESTY R&D Chief Operating Officer



ANNE HEATHERINGTON Head, Data Sciences Institute



WOLFRAM NOTHAFT Chief Medical Officer



тоѕніо ғилімото

STEFAN WILDT Head, Pharmaceutical Sciences and Translational Engine, Cell



JEREMY CHADWICK Head, Global Development Office<sup>†</sup>



WOLFGANG HACKEL Head, Global R&D Finance



Head, Global R&D Human



Head, Global R&D Communications

General Manager, Shonan Health Innovation Park (iPark)

### **OUR COMMITMENT TO OUR PEOPLE IS BEING RECOGNIZED**













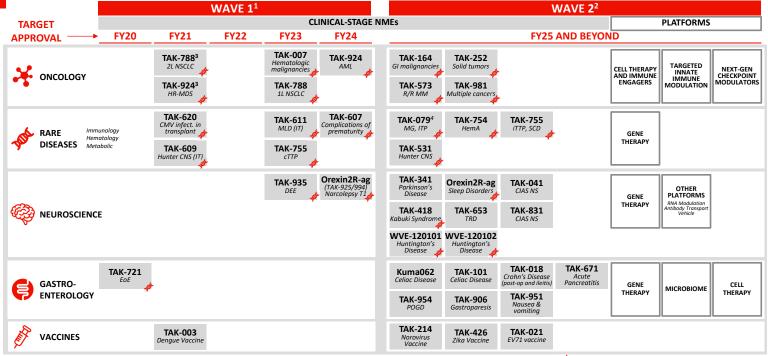






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