# TAKEDA ONCOLOGY

## WE ASPIRE TO CURE CANCER

June 8, 2020

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

The revenue of Shire plc ("Shire"), which was historically presented by Shire in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"), has 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 subsequently to the Shire acquisition, such as 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.

# Agenda

***All times below in Eastern Daylight Time (EDT)***

**8:00 – 8:05** *Costa Saroukos, Chief Financial Officer*

**8:05 – 8:20** *Teresa Bitetti, President, Global Oncology Business Unit*

- Takeda Overview
- Oncology Portfolio
- Commercial Updates

**8:20 – 8:40** *Chris Arendt, Head of Oncology R&D*

- Oncology Congress Data
- Pipeline Updates

**8:40 – 9:00** Question & Answer Session

# Today’s presenters

**TERESA BITETTI**
*President, Global Oncology Business Unit*

**CHRIS ARENDT**
*Head of Oncology R&D*

# Takeda Oncology Overview

TERESA BITETTI

*President, Global Oncology Business Unit*

# TAKEDA HAS BEEN PUTTING PATIENTS FIRST

## FOR OVER TWO CENTURIES

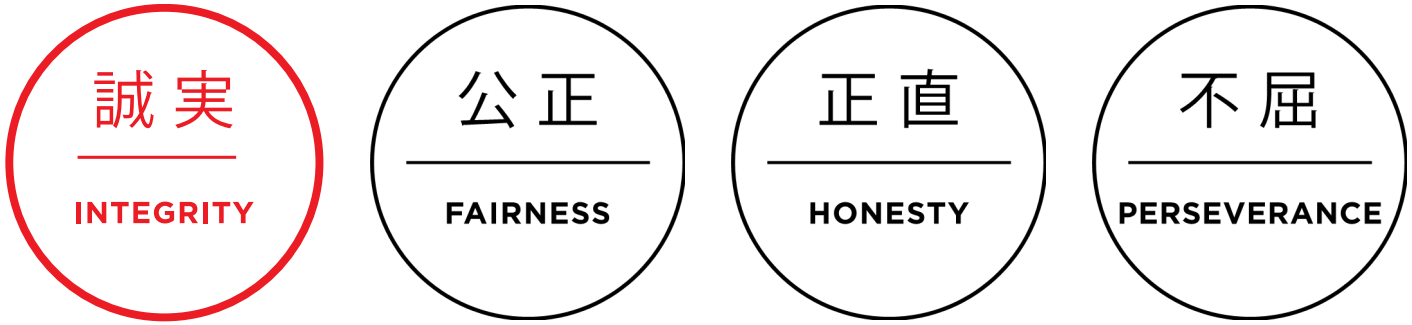
Since 1781, Takeda has been answering the question:

**How can we do more for patients?**

Takeda is a global, values-based, science-driven biopharmaceutical leader headquartered in Japan, committed to bringing **Better Health and a Brighter Future** to patients by translating science into highly innovative medicines.

# Our values define who we are and how we operate

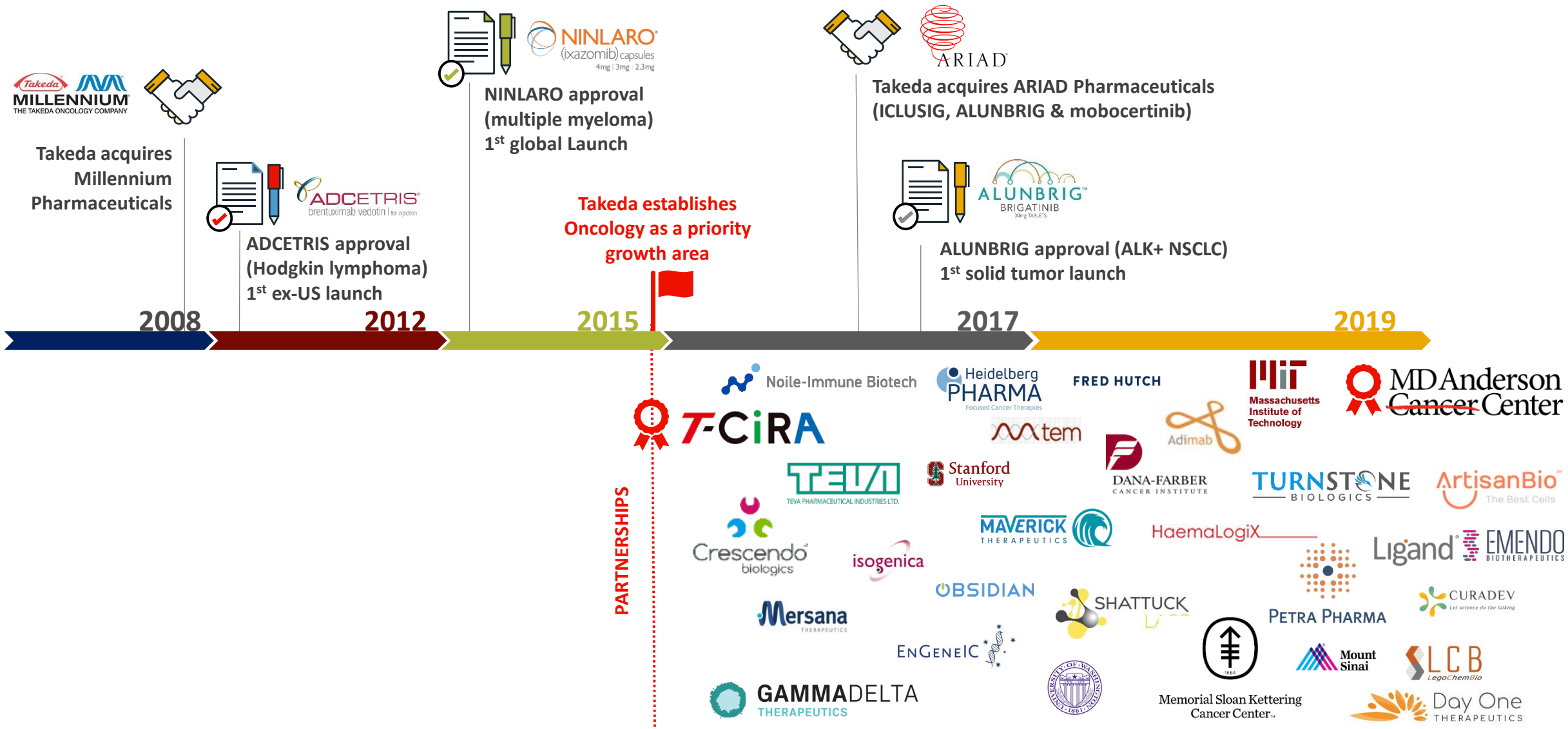
## TAKEDA-ISM




**We make decisions and take actions by focusing on the following priorities in this order:**

1. PUTTING THE **PATIENT** AT THE CENTER
2. BUILDING **TRUST** WITH SOCIETY
3. REINFORCING OUR **REPUTATION**
4. DEVELOPING THE **BUSINESS**

# Takeda has built a solid foundation in oncology

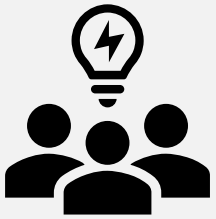



**Takeda Oncology has built a portfolio of global and regional oncology therapies spanning both hematologic malignancies and solid tumors**

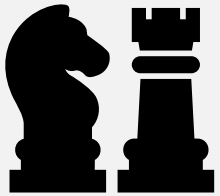
# WE ASPIRE TO CURE CANCER

| Where we are | What's next | Looking toward the future |
| --- | --- | --- |
| A leader in hematology + Strong growth based on execution | Build on expertise through expanded indications + new product launches | Differentiated I/O platforms and partnerships |

# Oncology Business Unit uniquely structured within Takeda to fit the needs of the cancer community

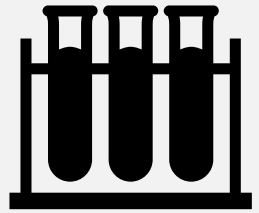


Leadership team and support to shepherd future growth



Structured for agility, on a legacy foundation

Proven growth and consistent performance

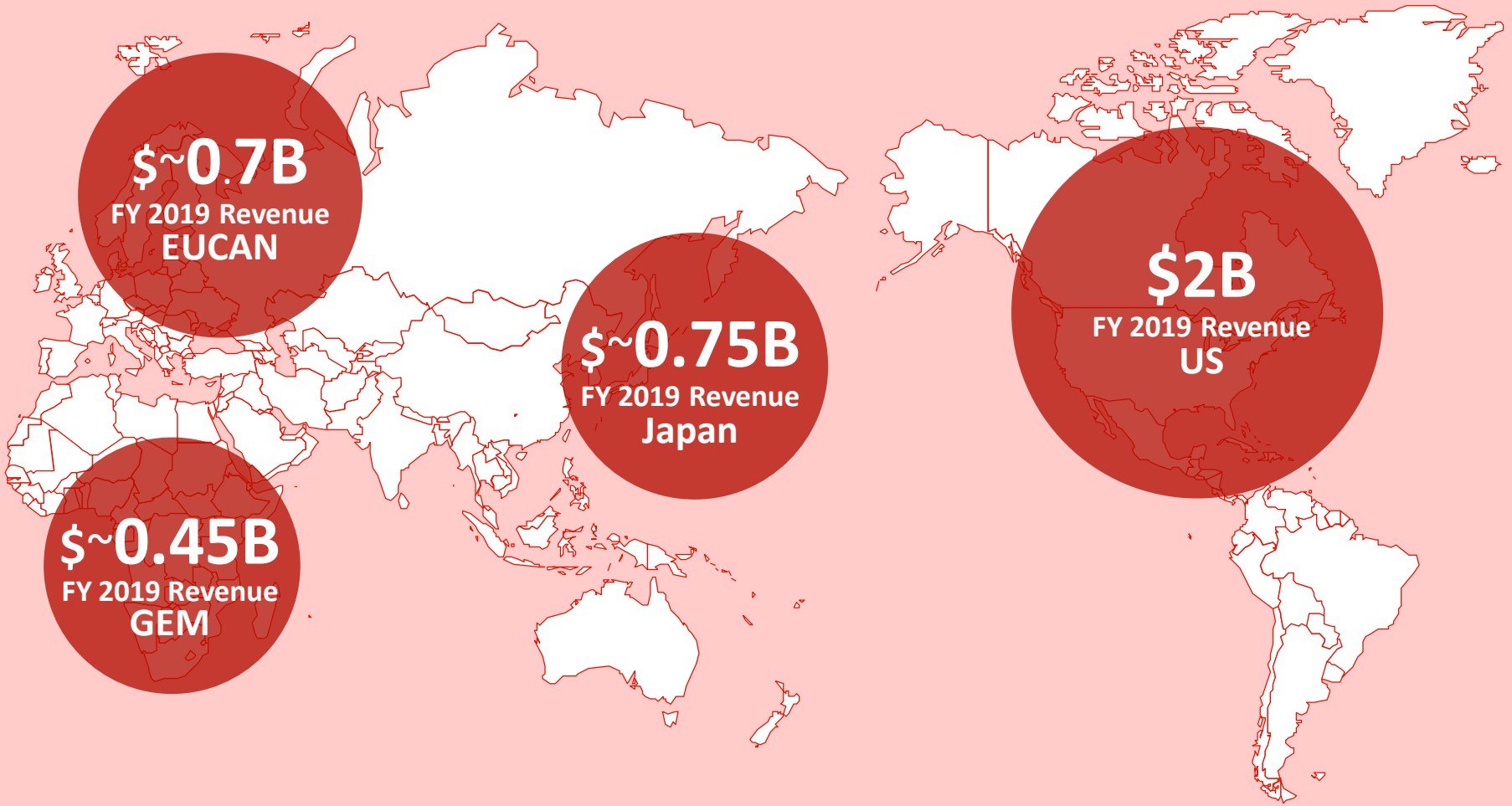


Diverse and robust pipeline

# We have a strong presence across major regions

**Global Oncology Revenue FY19: $~3.9B USD**

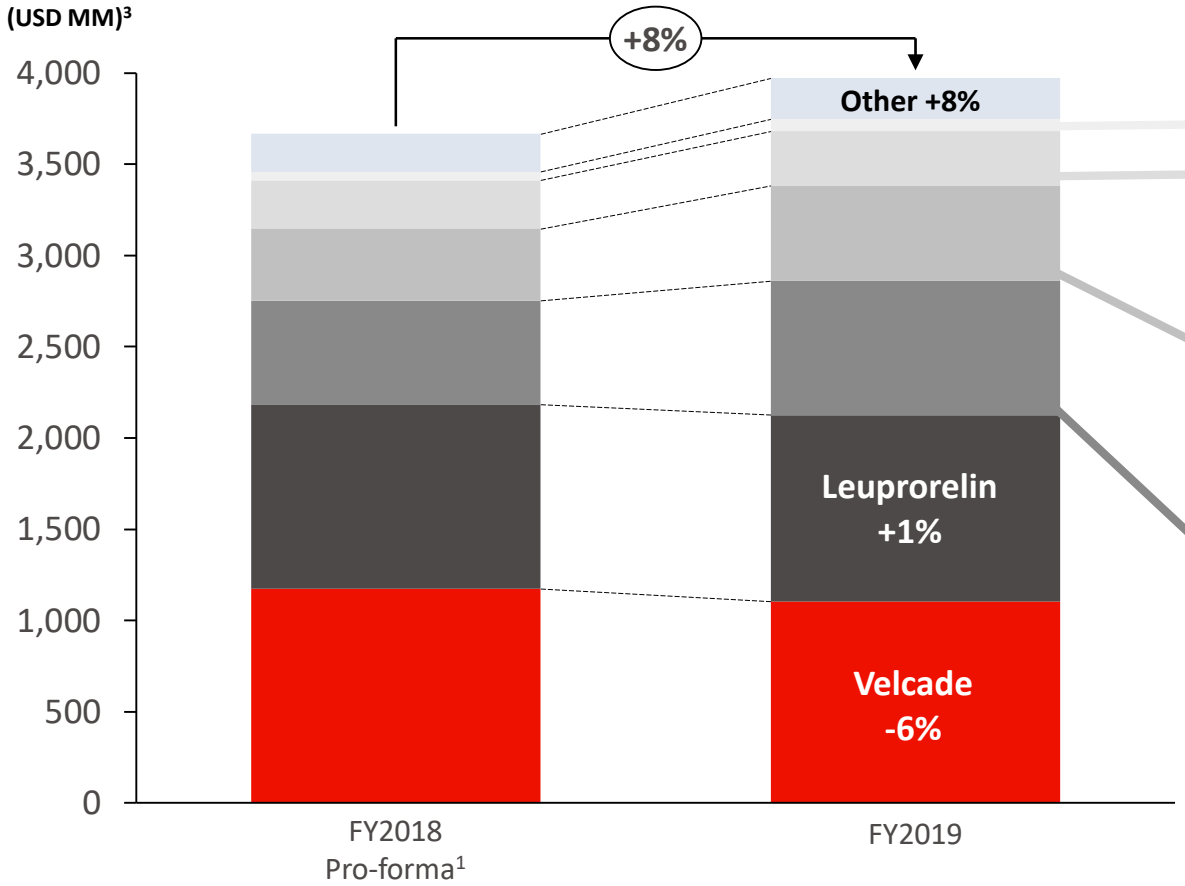
**More than 70 Countries Supported by Oncology**



# Key global and regional therapies fuel growth

## ONCOLOGY PORTFOLIO

FY2019, UNDERLYING REVENUE GROWTH[1]




ALUNBRIG™ BRIGATINIB 30mg TABLETS — **+43%** **$66MM USD**

ICLUSIG™ (ponatinib) tablets — **+13%** **$291MM USD**

ADCETRIS®[2] brentuximab vedotin for injection — **+33%** **$484MM USD**

NINLARO® (ixazomib) capsules 4mg | 3mg | 2.3mg — **+29%** **$712MM USD**

1. Legacy Shire's oncology revenue excluded
2. ADCETRIS is in-licensed from Seattle Genetics; Takeda has development and marketing rights outside of the U.S. and Canada
3. Calculated to USD for reference at JPY/USD of 109 yen.

Note: Absolute values are presented on an IFRS (reported) basis, calculated to USD for reference at JPY/USD of 109 yen

# Momentum in the last six months advances portfolio

## FIRST APPROVAL IN MAINTENANCE SETTING

- First approval in maintenance setting (post-SCT) granted in Japan in March 2020
- TOURMALINE-MM2 (frontline) did not meet primary endpoint; TOURMALINE-MM4 and US MM-6 data to be presented at EHA.

## APPROVALS IN NEWLY DIAGNOSED CD30+ PTCL AND R/R sALCL + HL

- Approved in the EU for previously untreated sALCL and in Japan, Brazil and South Korea for frontline PTCL
- Approved in China for relapsed or refractory system sALCL or Hodgkin lymphoma

## PRACTICE-CHANGING DATA READOUT

- OPTIC 2 data at ASCO show optimal benefit-risk profile in patients with difficult-to-treat CP-CML

## FIRST APPROVAL FOR FIRST-LINE USE

- Approved by the FDA and EU Commission as a first-line treatment for ALK+ advanced NSCLC based on results of ALTA 1L trial
- Filed in Japan in February 2020 for patients who have progressed after treatment with another ALK inhibitor

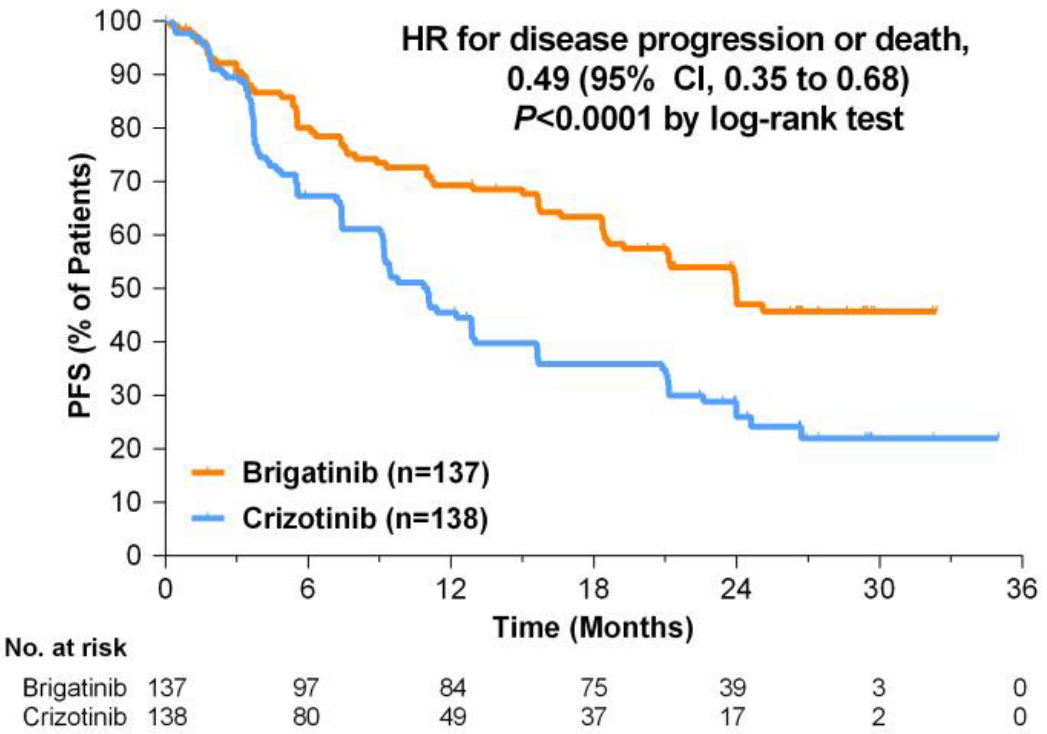
## NEW LAUNCH IN JAPAN

- Now available as a treatment for patients with curatively unresectable or metastatic renal cell carcinoma (RCC)

# ALUNBRIG achieves two early approvals in Q1, offers benefit for patients with brain metastases

- Granted **early approval by European Commission (EC)** in April as a monotherapy for adults with ALK+ NSCLC
- Received **U.S. FDA approval** as a first-line treatment for adults with ALK+ metastatic NSCLC as detected by an FDA-approved test in May, one month before PDUFA
- In the Phase 3 ALTA 1L trial, ALUNBRIG demonstrated.*
  - **Superior long-term efficacy** compared to crizotinib
  - **Superior efficacy in patients with brain metastases** at baseline with a confirmed intracranial ORR of 78% (95% CI: 52–94) versus 26% (95% CI: 10–48) with crizotinib
  - A safety profile generally consistent with the existing U.S. prescribing information

**PFS**




| Treatment | No. (%) of Patients With Events | Median PFS (95% CI) | 2-Year PFS, % (95% CI) |
|---|---|---|---|
| Brigatinib (n=137) | 63 (46) | 24.0 mo (18.5–NR) | 48 (39–57) |
| Crizotinib (n=138) | 87 (63) | 11.0 mo (9.2–12.9) | 26 (18–35) |

*As assessed by blinded independent review committee

# Takeda Oncology is at an inflection point

**10**

**Approved therapies with opportunities for label expansion**

**3**

**New Molecular Entities expected to launch by 2024**

**Because patients are waiting for new treatment options …**

# Oncology Congress Data

CHRIS ARENDT

*Head of Oncology R&D*

# We have recently presented compelling new data for some of our key therapies and late-stage pipeline

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY
Included today

ALUNBRIG™ BRIGATINIB 30mg TABLETS

NINLARO® (ixazomib) capsules 4mg | 3mg | 2.3mg
**TOURMALINE MM4**

ICLUSIG™ (ponatinib) tablets
**OPTIC IA**

ADCETRIS® brentuximab vedotin | for injection

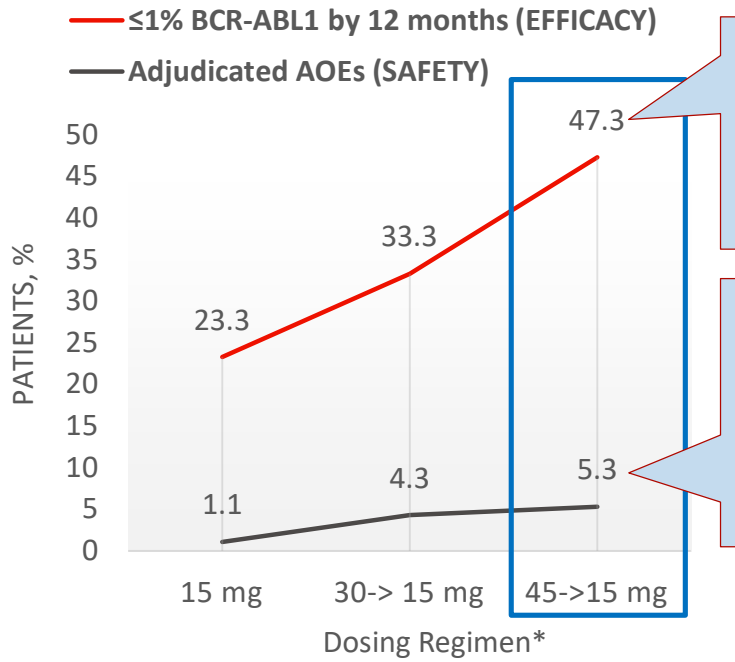
**pevonedistat**
**P2001 POC**

# Potentially practice-changing study data drives momentum for continued ICLUSIG growth

- ICLUSIG is the only third-generation pan-BCR-ABL1 inhibitor for CML and Ph+ ALL
- Data from OPTIC study presented at ASCO and EHA 2020 provides impetus for continued growth

| Historical Challenges | Impetus for Continued Growth |
|---|---|
| 1 Lack of clear dosing recommendation | ✓ Clarification on dosing regimen delivering optimal benefit |
| 2 Fear of cumulative and high AOEs | ✓ Refined understanding of AOE rates |
| 3 Niched perceptions and use of ICLUSIG | ✓ Clarification of benefit-risk of ICLUSIG |

## OPTIC Study Data: Potentially Practice-Changing for the Treatment of CP-CML




**Optimal benefit** achieved with a daily starting dose of **45mg followed by dose reduction to 15mg upon achieving ≤1% BCR-ABL1**

At this interim analysis, response-based dosing regimens resulted in a clinically manageable safety profile with **5.3% rate of adjudicated AOEs**

Note: AOE=Arterial Occlusive Events
*Patients starting on 45mg or 30mg had mandatory dose reduction to 15mg upon achieving ≤1% BCR-ABL1

# Maintenance treatment in MM patients not eligible for stem cell transplant supports NINLARO as a safe and effective drug

## PHASE 3 TOURMALINE-MM4 DATA

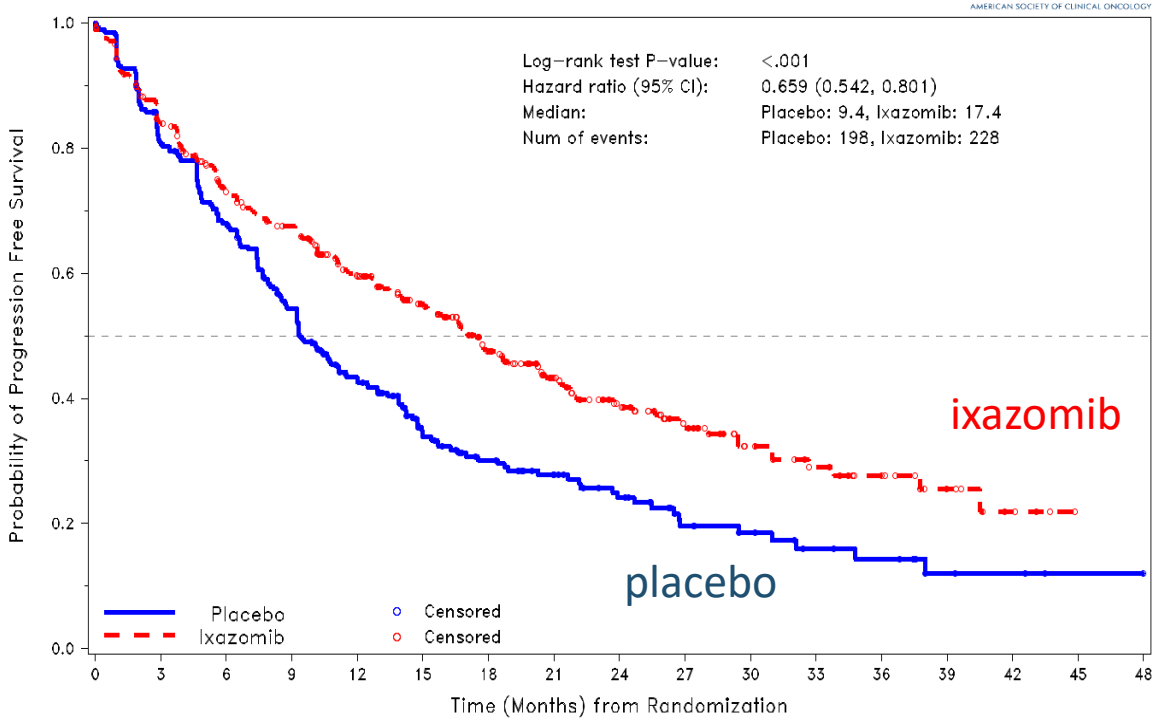
NINLARO® (ixazomib) capsules

**Significant overall improvement,** including 17.4 month median PFS compared with 9.4 months on placebo, and an overall 34% reduction in risk of progression / death

**Well-tolerated safety profile,** consistent with previously reported single-agent use

**First oral PI maintenance option** for non-ASCT NDMM patients.

**PFS**




**NINLARO addresses the need for an oral, tolerable proteasome inhibitor amenable to long-term administration**

* Ixazomib starts at 3 mg, and may escalate to 4 mg after 4 cycles if eligible

# Pevonedistat (TAK-924) results highly encouraging, particularly in HR-MDS, a patient group with no new treatments in over a decade

## PHASE 2 P2001 PROOF OF CONCEPT DATA

**Benefit across multiple clinically meaningful endpoints in HR-MDS** subgroup; adding pevonedistat to azacitidine doubled CR, and demonstrated potential to improve outcomes (OS, EFS[1])

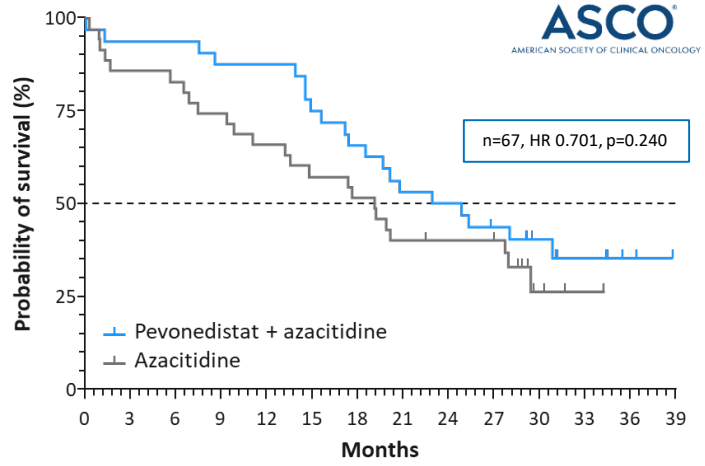
**Safety profile similar to azacitidine alone**

Phase 3 PANTHER trial fully enrolled; **potential to be the first novel agent for HR-MDS in over a decade**

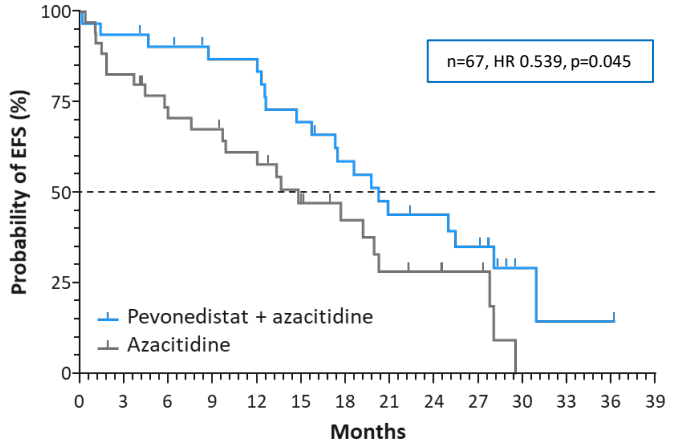
| Addressable Patients[2] | Next Inflection |
|---|---|
| 7k US \| 15-20k WW | 2H FY20: Ph 3 PANTHER pivotal readout |

HR-MDS

OS




EFS[1]




1. *EFS: Event Free Survival, defined as death or transformation to AML*
2. *HR-MDS*

# Oncology Pipeline Updates

# We are rapidly advancing a modality-diverse pipeline of meaningful near-term NMEs and differentiated immuno-oncology platforms

## ONCOLOGY CLINICAL NME PIPELINE

### POST-PROOF OF CONCEPT (WAVE 1[1])

TARGET APPROVAL →

| FY20 | FY21 | FY22 | FY23 | FY24 |
|---|---|---|---|---|
| | **TAK-788**[3] *2L NSCLC with EGFR exon 20 insertion mutation* | **TAK-924**[4] *HR-MDS* | **TAK-007** *Hematologic malignancies* | **TAK-924** *Unfit AML* |
| | | | **TAK-788** *1L NSCLC with EGFR exon 20 insertion mutation* | |

### PRE-PROOF OF CONCEPT (WAVE 2[2])

**Potential for acceleration with breakthrough data**

| | | | |
|---|---|---|---|
| **TAK-981**[5] *Multiple cancers* | **TAK-788** *HER2 mutant NSCLC* | **TAK-252** *Solid tumors* | |
| **TAK-573** *R/R MM* | **TAK-605**[6] *Multiple cancers* | **TAK-169** *R/R MM* | **TAK-676**[6] *Solid tumors* |

## DIFFERENTIATED I/O PLATFORMS AND PARTNERSHIPS

- **Innate immuno-modulation**
- **Novel-scaffold immune checkpoint platforms and oncolytic virus**
- **Next-gen cell therapy & immune engager platforms**

1. Projected approval dates depend on data read-outs; some Wave 1 target approval dates assume accelerated approval
2. Does not include TAK-079, currently in a Phase 1/2 study for R/R MM; TAK-079 will be developed in Rare Diseases indications myasthenia gravis and immune thrombocytopenic purpura
3. Projected approval date assumes filing on Phase 2 data
4. Projected approval date evolving based on emerging data and study progress
5. Wave 2 program with accelerated timeline
6. Expected new additions to the clinical pipeline with FPI projected in 1H FY20

All timelines are current best estimates and are subject to change due to COVID-19



Estimated dates as of May 13, 2020

# New medicines delivering near-term hope to patients, including mobocertinib, which received US FDA Breakthrough Therapy Designation

## mobocertinib[1] (TAK-788)

**POTENTIAL NEW STANDARD OF CARE FOR A SUBSET OF NSCLC PATIENTS WITH EXON 20 INSERTIONS**

BTD

## pevonedistat (TAK-924)

**PEVONEDISTAT IS POISED TO DELIVER MEANINGFUL PROGRESS IN HR-MDS AND AML**

### Current Development

| | |
|---|---|
| Exclaim | Registration enabling Phase 2 in 2L+ NSCLC EGFR exon 20 (data readout 1H FY20) |
| Exclaim-2<br>**(1-2% of NSCLC)**<br>**Patients: ~4k US \| ~20-30k WW** | Phase 3 global trial in 1L NSCLC EGFR exon 20 |
| **P2001** | Oral presentation at ASCO[2] and EHA[2]<br>Phase 2 pevonedistat + aza[3] vs. aza |
| PANTHER<br>**Patients: ~7k US \| ~15-20k WW** | Phase 3 in HR-MDS, CMML, LB AML.<br>pevonedistat + aza vs. aza<br>(data readout 2H FY20) |
| **PEVOLAM**<br>**(Unfit ~50% 1L AML)**<br>**Patients: ~12k US \| ~20-25k WW** | Phase 3 in 1L unfit AML.<br>pevonedistat + aza vs. aza<br>(data readout FY23[4]) |

### Expansion Opportunity

| | |
|---|---|
| **HER2 mutant solid tumors**<br>**(2-10% of breast, GI, bladder cancers)** | Phase 2 TAK-788 + HER2-ADC in HER2 mutant solid tumors start FY20[4] |
| **HER2 mutant NSCLC**<br>**(2-4% of NSCLC)**<br>**Patients: 2.6k US\| ~8k WW** | Dose expansion in NSCLC to inform go/no-go for Phase 3 development by FY22 |
| **Unfit AML**<br>**(Unfit ~50% 1L AML)** | Phase 2 in 1L unfit AML<br>pevonedistat + venetoclax + aza vs. venetoclax + aza. |

1. TAK-788 granted Breakthrough Therapy Designation for the treatment of patients with metastatic NSCLC with EGFR exon 20 insertion mutations who have progressed on or after chemotherapy.
2. ASCO: American Society of Clinical Oncology; EHA: European Hematology Association
3. AZA – Azacitidine
4. Impact of COVID-19 could delay timing

# Great momentum with 7 INDs filed since the start of FY19 for our early pipeline that harnesses the immune system in multiple manners

| | PLATFORM | PARTNER | PRE-CLINICAL | PHASE 1/2[1] |
|---|---|---|---|---|
| **INNATE IMMUNO-MODULATION** | *Attenukine™* | teva | | **TAK-573** *CD38-Attenukine R/R MM* |
| | *STING modulation* | Takeda | **TAK-500** *STING-ADC Solid Tumors* | **TAK-676** *STING Agonist Solid Tumors* |
| | *SUMOylation* | Takeda | | **TAK-981** *SUMO inhibitor Multiple cancers* |
| **NOVEL-SCAFFOLD IMMUNE CHECKPOINT PLATFORMS AND ONCOLYTIC VIRUS** | *Agonist-redirected checkpoints* | SHATTUCK LABS | **TAK-254** SL-115154 *CSF1R-Fc-CD40L Solid Tumors* | **TAK-252** SL-279353 *PD-1-Fc-OX40L Solid Tumors* |
| | *Oncolytic virus* | TURNSTONE BIOLOGICS | *Undisclosed* | **TAK-605** *FLT3L/mbIL12/anti-CTLA4 Solid Tumors* |
| | *Humabody Vh* | Crescendo | *Undisclosed* | |
| **NEXT-GEN CELL THERAPY & IMMUNE ENGAGER PLATFORMS** | *CAR-NK* | MD Anderson Cancer Center | *BCMA and two other targets* | **TAK-007** *CD19 CAR-NK Heme malignancies* |
| | *Cytokine + chemokine armed CAR-T* | Noile-Immune Biotech | **NIB-103** | **TAK-102** *GPC3 CAR-T Solid Tumors* |
| | *Next-gen CAR-T signaling domain* | Memorial Sloan Kettering Cancer Center | *Undisclosed* | **TAK-940** *CD19-1XX CAR-T Heme malignancies* |
| | *Gamma delta T cells* | GAMMADELTA THERAPEUTICS | **GDX012** | |
| | *Conditional T cell engagers* | MAVERICK THERAPEUTICS | **TAK-186** *EGFR-COBRA™ Solid Tumors* | |
| **OTHER** | *Shiga-like toxin A* | tem | *Undisclosed* | **TAK-169** *CD38-SLTA R/R MM* |
| | *CD38* | Takeda | | **TAK-079** *Anti-CD38 mAb R/R MM* |

**3** clinical-stage cell therapies

1. Includes Ph 1/2-ready programs with IND/CTN clearance

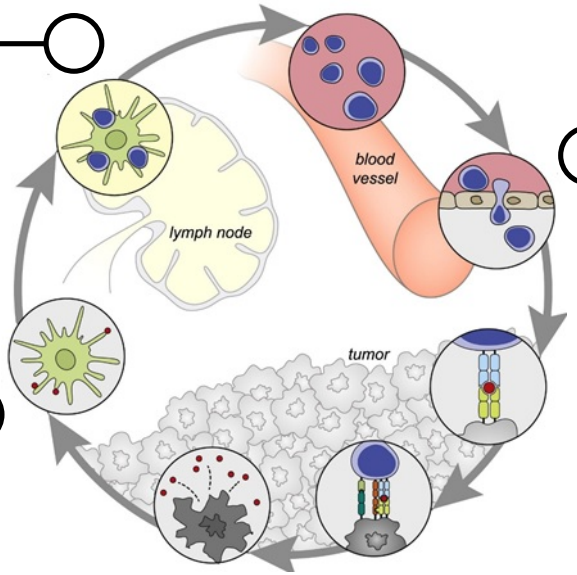
**Underline** = IND filed since start of FY19

# Takeda is a leader in applying the power of innate immunity to overcome limitations of current immunotherapies

## THE CANCER IMMUNITY CYCLE REQUIRES INNATE IMMUNITY

**Innate cells activate adaptive immune cells**

**Innate cells are "early responders" to orchestrate the immune response**




**Innate cells regulate tumor microenvironment**

*Adapted from Chen & Mellman, Immunity 2013*

**MECHANISMS OF ACTION LEVERAGING INNATE IMMUNITY MAY ENHANCE BREADTH, DEPTH, AND DURABILITY OF RESPONSE**

NK cells

SUMOylation inhibition

STING modulation

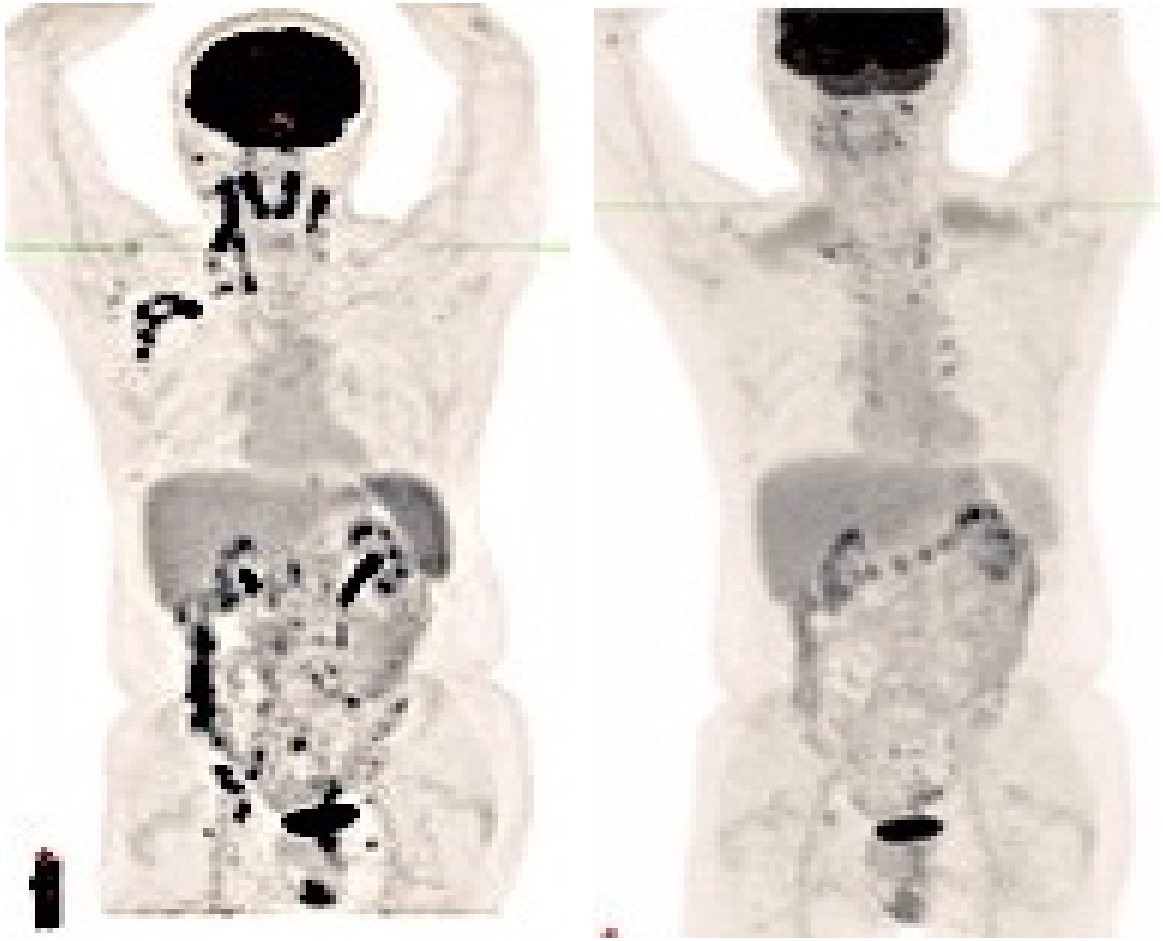
Attenukine™ platform

Oncolytic virus platform

# TAK-007 exhibits best-in-class potential for an off-the-shelf and better tolerated CD19 cell therapy

**47-year old male with relapsed transformed double-hit (c-myc / bcl-2) dlbcl**

Baseline Scan | Day 30 Post CAR19-NK



*Data from Dr. Katy Rezvani, MD Anderson Cancer Center*

## THE MOST ADVANCED CAR-NK THERAPY

- Phase 1/2: **complete responses in 8 of 11 patients** in heavily pretreated patients with B cell lymphomas*
- **No CRS, neurotoxicity or GVHD observed**
- Phase 1/2 expansion cohorts enrollment ongoing in CD19+ B cell malignancies

| Addressable Patients | Next Inflection |
|---|---|
| ~9k US \| ~15-25k WW | 2H FY20: Treat first patient with off-the-shelf cryopreserved product |

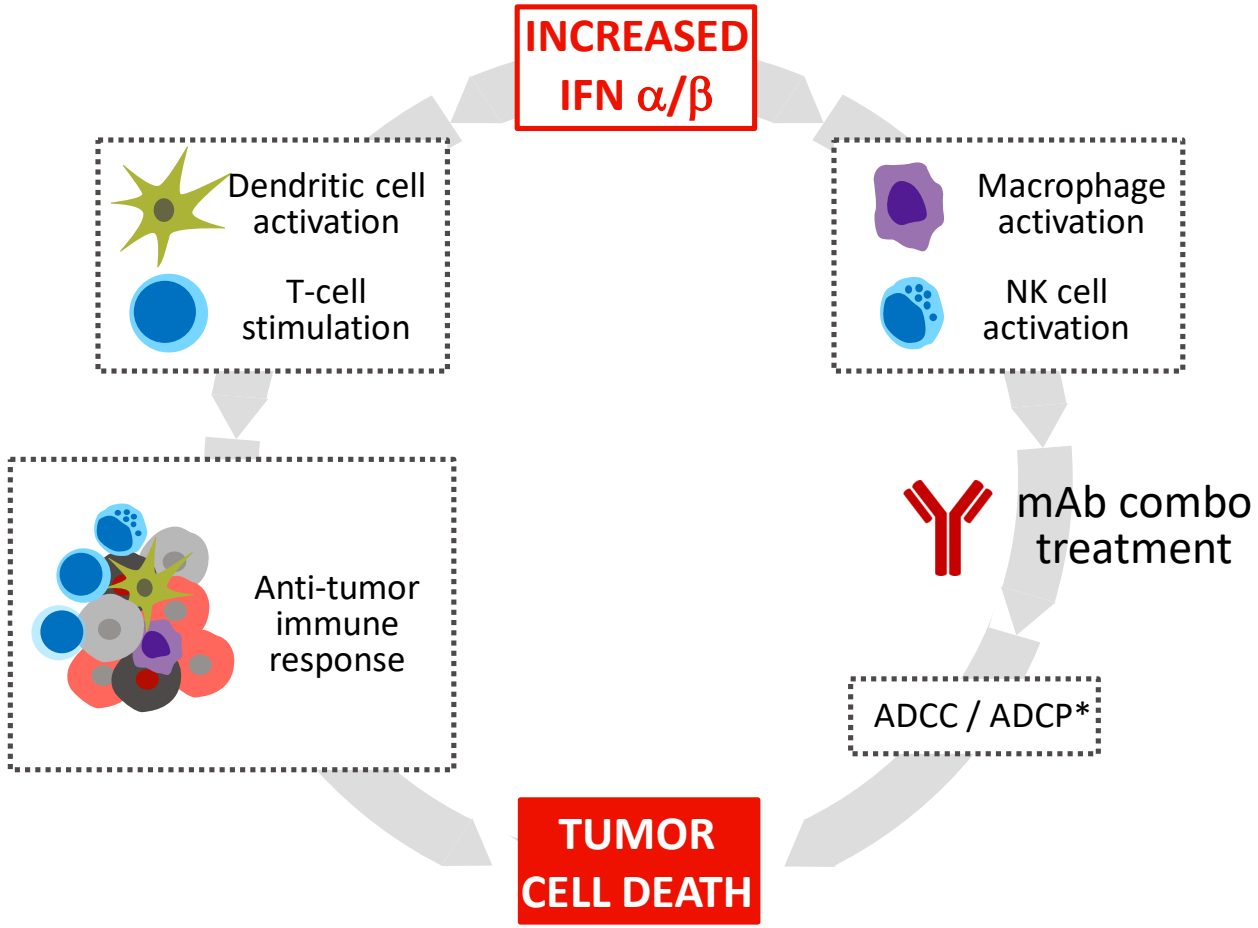
***"I didn't have any other options …** But it was scary knowing I would be No. 8 and would be getting the biggest dose ... I still get emotional when I talk about it."*

**J.C. Cox** Seagonville, TX

*NBC News, Feb 5, 2020*

# TAK-981 is a unique, first-in-class inhibitor of SUMOylation, which enhances the immune response through the interferon pathway

## REMOVES THE BRAKES ON IFN SIGNALING TO ENHANCE BOTH INNATE AND ADAPTIVE ANTI-TUMORAL IMMUNITY




- Responses seen in single-agent dose-escalation in solid tumors and in combination with rituximab in NHL
- Initial development in combination with anti-PD1 in solid tumors and R/R non-Hodgkin lymphoma

**POTENTIAL ANTI-VIRAL EFFICACY IN COVID-19+ CANCER PATIENTS**

FDA support to dose patients in ongoing oncology studies; concept to study amendment in ~1 month

**Next Inflection**

1HFY20: Initiate COVID-19 treatment arm for patients with metastatic or relapsed / refractory hematologic malignancies

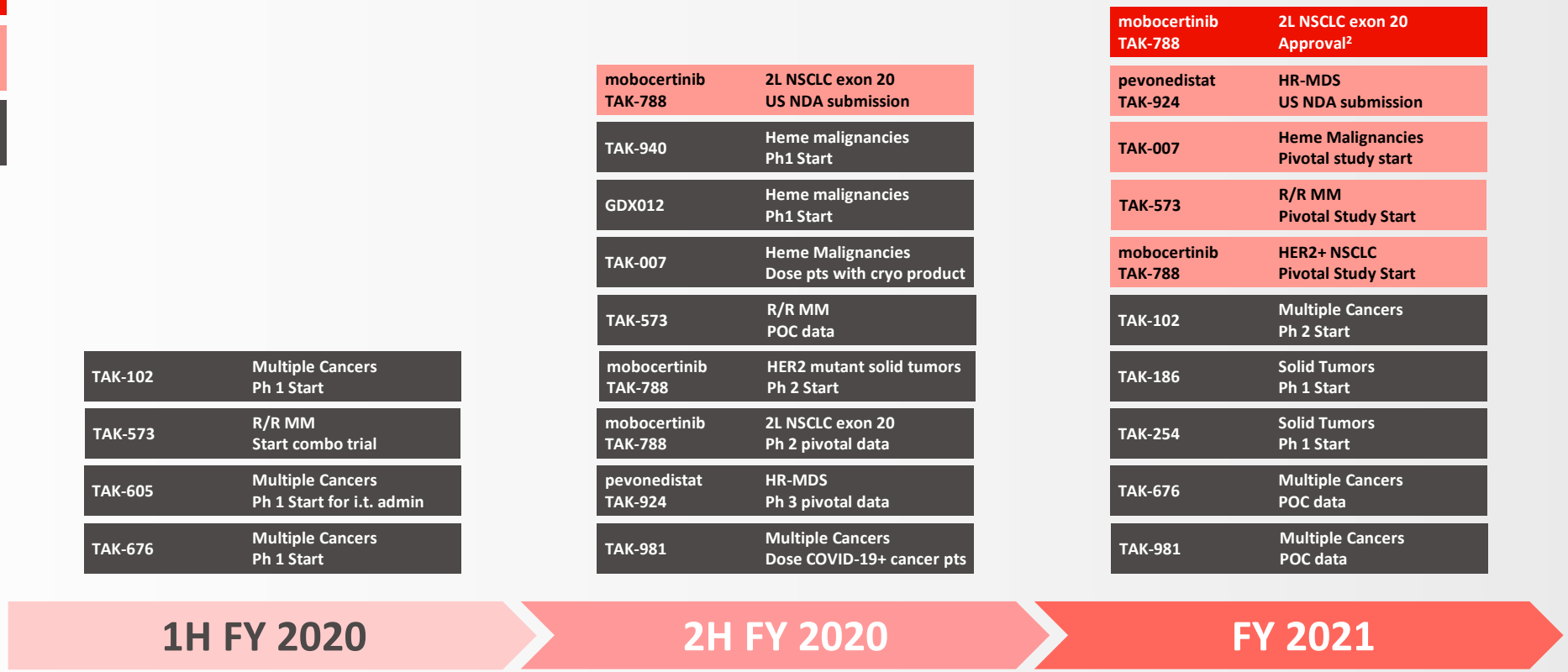
*ADCC: antibody-dependent cellular cytotoxicity; ADCP: antibody-dependent cellular phagocytosis

# We are excited by the potential of our NME pipeline, looking ahead to other potential milestones[1] through FY21

**FIRST APPROVALS**

**PIVOTAL STUDY STARTS AND FIRST SUBMISSIONS**

**PH 1/2 STUDY STARTS AND DATA READOUTS**

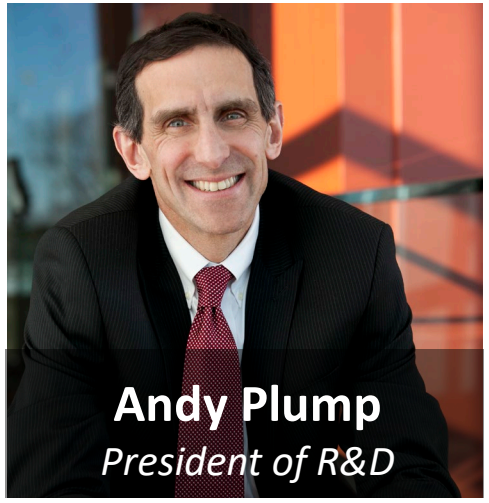



1. Potential key milestone dates as of May 13, 2020. The dates included herein are estimates based on current data and are subject to change
2. EU, China approval projected in 2022

Note: Takeda Fiscal Year begins on April 1 and ends on March 31 of each year

# Questions & Answers









# THANK YOU