



SCIENCE DRIVEN COMPANY WITH A FOCUSED MIND







# R&D DAY AGENDA – TOKYO, NOVEMBER 21, 2019



TIME	AGENDA					
11:00 – 11:05	Welcome and Introduction of Presenters					
	Ayako lwamuro, Investor Relations, Global Finance					
11:05 – 11:45	Realizing the Potential of Plasma-derived Therapies					
	Julie Kim, President, Plasma-Derived Therapies Business Unit					
11:45 – 12:15	A New Dedicated Focus on Innovative, Sustainable Solutions for Plasma-Derived Therapies					
	Christopher Morabito, M.D., Head of R&D, Plasma-Derived Therapies					
12:15 - 12:45	Q&A session					
12:45 - 13:25	Lunch Break					
13:25 – 13:35	Welcome back and Introduction of Presenters					
	Ayako lwamuro, Investor Relations, Global Finance					
13:35 – 13:45	Takeda: A Global Values-Based, R&D-Driven Biopharmaceutical Leader					
15.55 - 15.45	Christophe Weber, President & CEO Takeda					
13:45 – 14:15	Translating Science into Highly Innovative, Life-changing Medicines					
13.43 - 14.13	Andy Plump, President R&D					
14:15 – 14:40	Oncology and Cell Therapies with Spotlight on CAR-NK					
14.13 - 14.40	Chris Arendt, Head Oncology Drug Discovery Unit					
	Spotlight on Oncology Opportunities					
14:40 - 15:00	• TAK-788: Rachel Brake, Global Program Lead					
	Pevonedistat: Phil Rowlands, Head Oncology Therapeutic Area Unit					
15:00 - 15:20	Break					
15:20 – 15:45	Rare Diseases & Gene Therapy					
15.20 - 15.45	Dan Curran, Head Rare Disease Therapeutic Area Unit					
15:45 – 16:00	Spotlight on Orexin2R agonists					
13.43 - 10.00	Deborah Hartman, Global Program Lead					
16:00 – 16:20	Therapeutic Area Focus in GI with Spotlight on Celiac Disease					
10.00-10.20	Asit Parikh, Head GI Therapeutic Area Unit					
16:20 – 17:00	Panel Q&A Session					
17:00	Drinks reception					



# TRANSLATING SCIENCE INTO HIGHLY INNOVATIVE LIFE-CHANGING MEDICINES



Andy Plump MD, PhD
President R&D
Takeda Pharmaceutical Company Limited
Tokyo

November 21, 2019

Better Health, Brighter Future

### WHAT YOU WILL HEAR TODAY



1

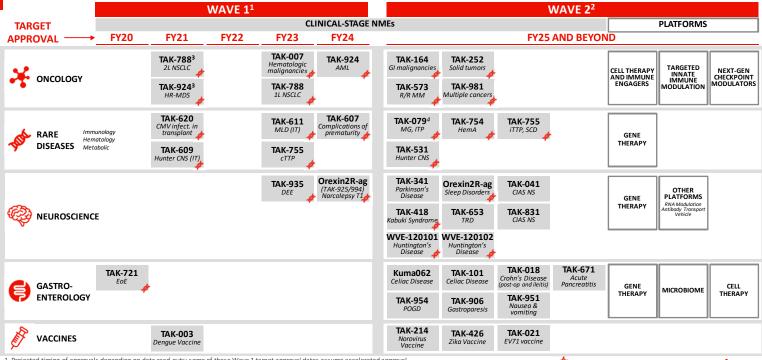
Our portfolio and pipeline will drive growth and offset key patent expirations 2

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

22

### **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 adalimumab 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

## **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

24

## WE ARE DOING MORE FOR OUR PATIENTS





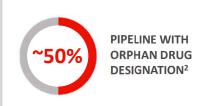


NEW MOLECULAR ENTITY CLINICAL STAGE ASSETS

~4,500
R&D EMPLOYEES
GLOBALLY









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



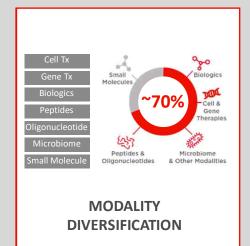
"There is a considerable need for improved treatments for individuals with NT1, which is caused by the loss of orexinproducing neurons in the brain"



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

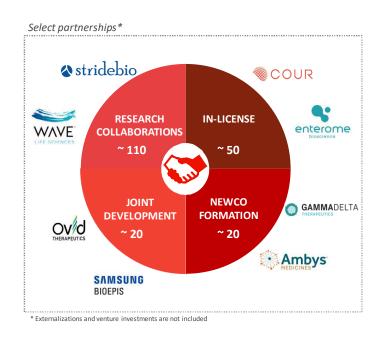
Indications terminated or externalized since FY18

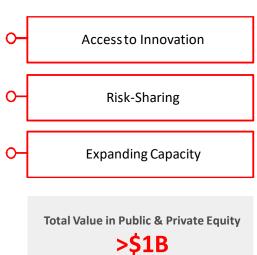
> **FAST GO / NO-GO DECISION MAKING**

> > 26

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







# WE ARE NURTURING INNOVATION WHEREVER IT OCCURS





Representative examples only

28

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





Minimize internal spend and infrastructure

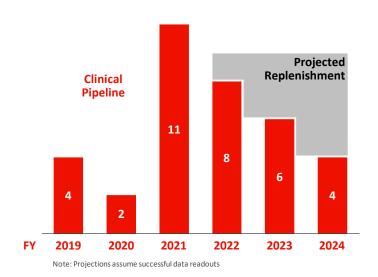
Smaller trials, lower costs, potential longer exclusivity

Success driven milestone payments

#### A RESEARCH ENGINE FUELING A SUSTAINABLE PIPELINE



#### POTENTIAL NME PIVOTAL STUDY STARTS BY YEAR



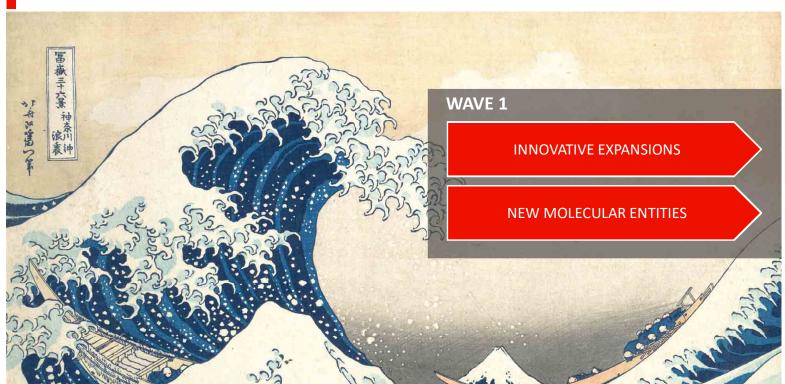
#### **IMPROVED PRODUCTIVITY**

- 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

30

### 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) ALUNBRIG 1L Non Small Cell Lung Cancer 2020 NINLARO ONC ND MM Maintenance (non-SCT and post-SCT) 2020 / 2022 TAKHZYRO Bradykinin Mediated Angioedema 2024 vonvendi \* Rare Prophylactic Treatment of von Willebrand Disease 2021 Ulcerative Colitis, Crohn's Disease (subcutaneous formulation) 2019 / 2020 **TEntyvio** Graft versus Host Disease (prophylaxis) 2022 GI AL FISEL 2021 Complex Perianal Fistulas

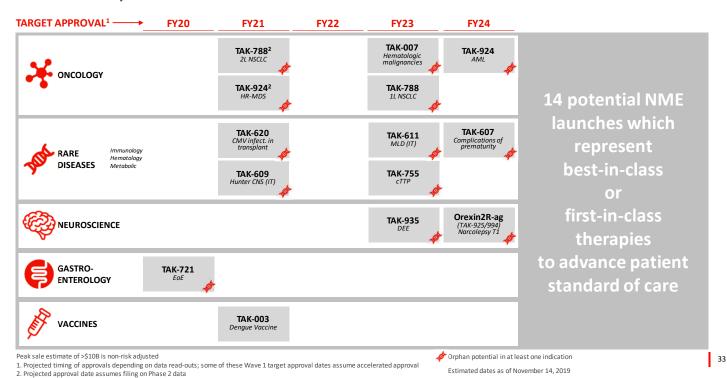
LECT REGIONAL EXPANSIONS								
Region		Therapies				Therapies		
China	Entyvio Vedalizumab ALUN BRIGG	NBRIG TAKHZYRO Ilanadelumab-flyol rjection	VPRIV° velaglucerase alfa for injection	ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated]	Japan	Takecab	relugolix, cabozantinib niraparib	

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

32

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





<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	NTIALFIRS	T-IN-CLASS OR BE	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
		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
<b>FREE</b>	RARE DISEASES Immunology Hematology Metabolic	maribavir (TAK-620)	UL97 kinase inh	CMV infect. in transpl.	2021	~7 - 15k	~25 - 45k
		TAK-607	IGF-1/IGFBP3	Complications of prematurity	2024 <sup>5</sup>	~25k	~80 - 90k
		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
(C)	NEUROSCIENCE	Orexin programs	Orexin 2R agonist	Narcolepsy Type 1	2024	70 - 140k	300k - 1.2M
		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
AT THE PERSON NAMED IN COLUMN TO THE	VACCINES	● TAK-003	Vaccine	Dengue	2021	~32M	~1.8B

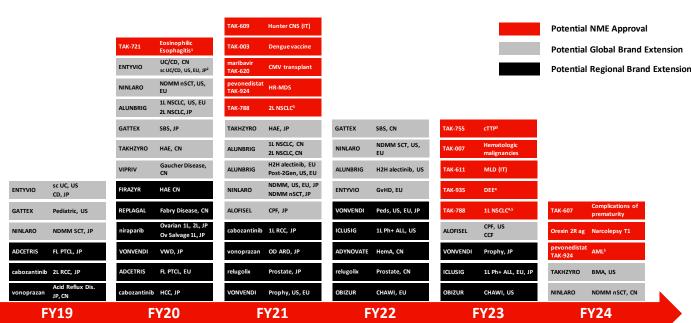
- Projected timing of approvals depending on data read-outs; some of these target approval dates assume accelerated approval
   Estimated number of patients projected to be eligible for treatment in markets where the product is anticipated to be
- commercialized, subject to regulatory approval

  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 annroval in 2023
- 2. US approval for sc CD, EU approval for sc UC & CD, Japan approval for sc CD
- 3. Includes approval in China 4. China approval in 2024
- 5. New indication for currently unapproved asset

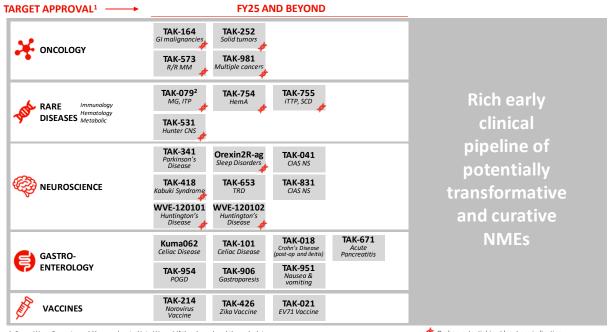
#### **SUSTAINED GROWTH BEYOND FY25**





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





- 1. Some Wave 2 assets could be accelerated into Wave 1 if they have breakthrough data
- TAK-079 to be developed in Rare Diseases indications myasthenia gravis (MG) and immune thrombocytopenic purpura (ITP) (FPI projected for 2H FY19)

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

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



#### TARGET APPROVAL

**→** 

#### **FY25 AND BEYOND**



ONCOLOGY

CELL THERAPIES AND IMMUNE ENGAGERS CAR-T GammaDelts

MSKCC, Noile-Immune CAR-T GammaDelta T. -CIRA, Takeda Conditional T cc CAR-NK engagers MD Anderson Maverick TARGETED INNATE IMMUNE MODULATION Attenukine Tevo STING CuraDev, Takeda SUMOylation Takeda NEXT-GEN CHECKPOINT MODULATORS Agonist-redirected checkpoints Shattuck Humabodies Crescendo



RARE DISEASES Immunology Hematology Metabolic GENE THERAPY

Hemophilia
Lysosomal Storage Diseases

NEUROSCIENCE

GENE THERAPY Neurodegenerative Diseases StrideBio OTHER PLATFORMS
RNA Modulation
Wave, Skyhawk
Antibody Transport Vehicle
Denali

GASTRO-ENTEROLOGY

GENE THERAPY Liver Ambys MICROBIOME FIN-524 FInch Microbial Consortia NuBiyota

CELL THERAPY
Ambys

Harnessing the potential of cell and gene therapies and other diverse modalities

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

Estimated dates as of November 14, 2019

38

## **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**









40

#### LIVING OUR VALUES THROUGHOUT THE INTEGRATION PROCESS





\* Where legally cleared

41

#### STRONG LEADERSHIP EXECUTING ON OUR VISION





ASIT PARIKH Head, Gastroenterology Therapeutic Area Unit



PHIL ROWLANDS Head, Oncology Therapeutic Area Unit



DAN CURRAN Head, Rare Disease



EMILIANGELO RATTI Head, Neuroscience



Head, Neuroscienc





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

New hire





STEVE HITCHCOCK



NENAD GRMUSA Head, Center for External Innovation



GEORGIA KERESTY R&D Chief Operating Officer



ANNE HEATHERINGTON Head, Data Sciences Institute







STEFAN WILDT Head, Pharmaceutical Sciences and Translational Engine, Cell



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





ERIKA MARDER Head, Global R&D Human Resources



Communications



#### 42

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















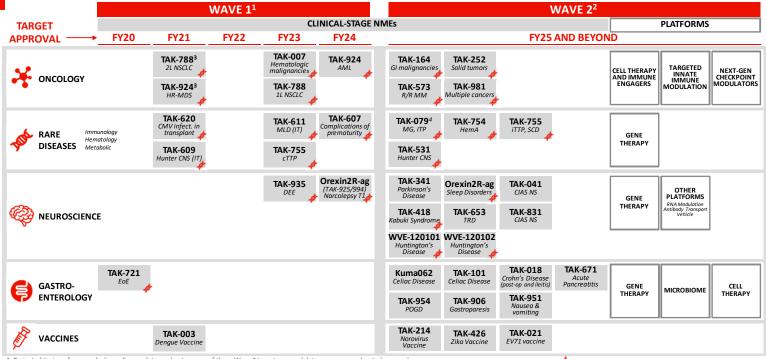






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