Takeda R&D: Translating Science into Highly Innovative, Life-Changing Medicines

Takeda is an R&D driven, global biopharmaceutical leader. For over 200 years, we've focused on bringing better health and a brighter future to people around the world by translating science into life-changing medicines that make a critical difference for patients. We have earned our place among the top 10 global innovators and we are confident in our ability to execute on our near-term and sustained growth opportunities through 2025 and beyond.

OVER THE NEXT SEVERAL YEARS, OUR PIPELINE IS PROJECTED TO DELIVER VALUE IN TWO DISTINCT WAVES.

Takeda supports dedicated R&D efforts across three areas: Innovative Biopharma, Plasma Derived Therapies (PDT) and Vaccines. We have a diverse portfolio of approved medicines and we are committed to innovative expansions of our 14 global growth brands as we believe they could deliver significant benefit to new patients.

The R&D engine for Innovative Biopharma, the largest component of our R&D investment, has produced exciting new molecular entities (NMEs) that represent potential best-in-class and/or first-in-class medicines in areas of high unmet medical need across our core Therapeutic Areas: Oncology, Rare Diseases, Neuroscience and Gastroenterology. Over the past several years, and more recently bolstered by our acquisition of Shire, we have increased our focus on more targeted patient populations where there is the potential for greater therapeutic benefit, smaller and less costly development programs, and faster tracks to registration with enhanced patent protection and marketing rights.

WAVE 1: NEAR-TERM GROWTH

GLOBAL BRAND EXPANSION AND 12 NMES WITH THE POTENTIAL FOR 15 LAUNCHES THROUGH FY2024

14 GLOBAL GROWTH BRANDS

Our 14 global growth brands continue to generate significant opportunities through new indications and geographic expansion. **With more than 20 ongoing pivotal studies and 12 applications under review by regulatory agencies, we anticipate our global growth brands to generate at least 20 additional launches over the next five years.** We also intend to deliver at least 15 transformative medicines to patients in China by 2025.[1] Our 14 global growth brands will sustain us for the next 5 years through geographic expansion and additional indications.

For our 14 global growth brands, we are targeting the following extensions through FY24:

FY20	FY21	FY22	FY23	FY24
ALUNBRIG *1L NSCLC; US, EU, JP* *2L NSCLC; JP*	**ALUNBRIG** *1L NSCLC; CN* *2L NSCLC; CN*	**TAKHZYRO** *HAE; JP*	**NINLARO** *NDMM nSCT; US, EU* *NDMM SCT; US, EU*	**TAKHZYRO** *BMA; US*
ENTYVIO *sc UC/CD; EU* *sc UC; JP*	**ALUNBRIG** *H2H alectinib; EU* *Post-2Gen; US, EU*	**ENTYVIO** *sc UC; US* *sc CD; US, JP*	**ENTYVIO** *GvHD; EU*	**NINLARO** *NDMM nSCT; CN* *NDMM SCT; CN*
TAKHZYRO *HAE; CN*	**NINLARO** *NDMM nSCT; JP*	**ALUNBRIG** *H2H alectinib; US* *ALK+ NSCLC; CN*	**ALOFISEL** *CPF; US*	**ENTYVIO** *sc UC/CD; CN*
VPRIV *Gaucher Disease; CN*	**ALOFISEL** *CPF; JP*	**ADYNOVATE** *HemA; CN*	**GATTEX** *SBS; CN*	**ALOFISEL** *CPF; CN*
	GATTEX *SBS; JP*			

12 NMES WITH THE POTENTIAL FOR 15 BEST-IN-CLASS/FIRST-IN-CLASS LAUNCHES

The main driver for new product launches in the near term are our unique NMEs which represent several potential best-in-class / first-in-class therapies. Of these programs, nine are in registration-enabling studies and we intend to have data read outs in the next 3-5 years. These anticipated product launches are intended to fuel our growth trajectory while our next-generation platforms mature.

TARGET APPROVAL[2] →	FY20	FY21	FY22	FY23	FY24
ONCOLOGY		**mobocertinib** *2L NSCLC with EGFR exon 20 insertion mutation*[3]	**pevonedistat** *HR-MDS*	**mobocertinib** *1L NSCLC with EGFR exon 20 insertion mutation*	**pevonedistat** *Unfit AML*
				TAK-007 *CD19+ hematologic malignancies*	
RARE DISEASES *Immunology* *Hematology* *Metabolic*		**maribavir** *R/R CMV infect. in transplant*	**maribavir** *1L CMV infect. in HSCT*	**TAK-611** *MLD (IT)*	
		TAK-609 *Hunter CNS (IT)*		**TAK-755** *cTTP*	
NEURO-SCIENCE				**soticlestat** *DEE*	**Orexin2R-ag** *(TAK-925/994)* *Narcolepsy T1*
GASTRO-ENTEROLOGY	**TAK-721** *EoE*				
VACCINES		**TAK-003** *Dengue Vaccine*			
PDT	**CoVIg-19**[4] *COVID-19 H-IG* *(Formerly TAK-888)*				

[1] Of the >15 new medicines, 6 represent our global brands: Entyvio®, Alunbrig®, Ninlaro®, Vpriv®, Takhzyro®, Adynovate®
[2] Projected approval dates depend on data read-outs; some Wave 1 target approval dates assume accelerated approval
[3] Approval date assumes filing on Phase 2 data
[4] Expected new addition to the clinical pipeline with FPI projected in 1H FY20

All timelines are current best estimates as of July 31, 2020 and are subject to change due to impact by COVID-19

WAVE 2: SUSTAINED GROWTH (FY2025 AND BEYOND)

>20 PROGRAMS AND NEXT-GENERATION PLATFORMS

Our research engine, comprised of our internal research capabilities and external partnerships, is quickly advancing a steady stream of next generation therapies designed to provide **transformative or curative potential** for targeted populations with high unmet need, in our core Therapeutic Areas. These programs are based on targets with strong human validation, represent diverse modalities and leverage new platform capabilities in cell therapy, gene therapy and data sciences. *Programs with strong efficacy data may enable accelerated development and accelerated regulatory pathways.*

TARGET APPROVAL[5] →	FY25/26		FY27 AND BEYOND			
ONCOLOGY	**TAK-981** *Multiple cancers*	**mobocertinib** *HER2 mutant NSCLC*	**TAK-252** *Solid tumors*			
	TAK-573 *R/R MM*	**TAK-605** *Multiple cancers*	**TAK-169** *R/R MM*	**TAK-676** *Solid tumors*		
RARE DISEASES *Immunology Hematology Metabolic*			**TAK-607** *Complications of prematurity*			
	TAK-755 *iTTP, SCD*	**TAK-079** *MG, ITP*	**TAK-754** *HemA*			
NEURO-SCIENCE	**TAK-935** *CRPS*	**WVE-120101** *Huntington's Disease*				
	Orexin2R-ag *Sleep disorders*	**WVE-120102** *Huntington's Disease*	**TAK-341** *Parkinson's Disease*	**TAK-041** *Anhedonia in MDD*	**TAK-653** *TRD*	**TAK-831** *CIAS NS*
GASTRO-ENTEROLOGY	**TAK-062** *Celiac Disease*	**TAK-101** *Celiac Disease*	**TAK-018** *Crohn's Disease (post-op and ileitis)*	**TAK-671** *Acute Pancreatitis*		
	TAK-951 *Nausea & vomiting*	**TAK-906** *Gastroparesis*	**TAK-954** *POGD*	**TAK-039** *Hepatic encepha-lopathy*		
VACCINES		**TAK-426** *Zika Vaccine*	**TAK-214** *Norovirus Vaccine*			

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

More than 4,500 employees across Takeda R&D are advancing our near-term catalysts with a sense of urgency while building our next-generation platforms to sustain our long-term growth so that we may fulfill our mission to deliver better health and brighter futures to even more patients around the world.

GLOSSARY OF ABBREVIATIONS

1L	first line
2L	second line
AML	acute myeloid leukemia
BMA	bradykinin mediated angioedema
CCF	complex cryptoglandular fistula
CD	Crohn's disease
CIAS	cognitive impairment associated with schizophrenia
CMV	cytomegalovirus
CN	China
CNS	central nervous system
CPF	complex perianal fistula
CRPS	complex regional pain syndrome
cTTP	congenital thrombotic thrombocytopenic purpura
DEE	developmental and epileptic encephalopathies
EOE	eosinophilic esophagitis
EU	European Union
GI	gastrointestinal
GvHD	graft versus host disease
HAE	hereditary angioedema
H2H	head to head
HemA	hemophilia A
HR MDS	high-risk myelodysplastic syndromes
IHM	immunology hematology metabolic
IT	intrathecal
ITP	idiopathic thrombocytopenic purpura
iTTP	immune thrombotic thrombocytopenic purpura
JP	Japan
MG	myasthenia gravis
MLD	metachromatic leukodystrophy
NDMM	newly diagnosed multiple myeloma
NME	new molecular entity
NSCLC	non-small cell lung cancer
nSCT	non stem cell transplant
NS	negative symptoms
Orexin2R-ag	orexin 2 receptor agonist
PDT	Plasma Derived Therapies (business unit)
Ped	pediatric
POC	proof of concept
Post-2 gen	after 2nd generation ALK inhibitor
Post-op	post-operative
POGD	post-operative gastrointestinal dysfunction
R&D	research and development
RNA	ribonucleic acid
R/R MM	relapse/refractory multiple myeloma
SBS	short bowel syndrome
sc	subcutaneous formulation
SCD	sickle cell disease
SCT	stem cell transplant
T1	type 1
TRD	treatment resistant depression
UC	ulcerative colitis
US	United States

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IMPORTANT NOTE

FORWARD-LOOKING STATEMENTS

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