Our Pipeline: Delivering Waves of Innovation for Patients

For 240 years, Takeda has 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 to patients.

Innovative Biopharma R&D Focus


Oncology


Rare Genetics & Hematology


Neuroscience


Gastroenterology

Strategic Investments


Plasma-Derived Therapies


Vaccines

Takeda supports R&D efforts across three areas: Innovative Biopharma, Plasma-Derived Therapies (PDT) and Vaccines. The R&D engine for Innovative Biopharma, our largest R&D investment, has produced a diverse and dynamic pipeline in areas of high unmet medical need across our core therapeutic areas where we have deep expertise in Oncology, Rare Genetics & Hematology, Neuroscience and Gastroenterology.

Successive Waves of Innovation Contribute to Sustained Growth

Our pipeline is positioned to deliver both near-term and sustained growth to Takeda in two waves:

~1 Wave 1: Near-Term Growth

Takeda is positioned to deliver near-term growth through global brand expansions and its **Wave 1** pipeline, which includes multiple best-in-class/first-in-class new molecular entities (NMEs) with potential for approvals through Takeda's fiscal year (FY) 2024. Our first Wave 1 NME EXKIVITY™ has been approved by the U.S. FDA as the first oral therapy specifically designated for patients with EGFR Exon20 insertion+ non-small cell lung cancer (NSCLC). In addition, three other Wave 1 programs (maribavir, Eohilia and TAK-003) have been submitted for regulatory review.

In addition, Takeda is supporting global access to two different COVID-19 vaccines. We are partnering with Novavax to develop, manufacture and commercialize 250 million doses of their COVID-19 vaccine (TAK-019) in Japan. We are importing and distributing 100 million doses of Moderna's mRNA COVID-19 vaccine (TAK-919) working with Moderna and Japan's Ministry of Health Labour and Welfare (MHLW).

≈2 Wave 2: Sustained Growth

Wave 2 of our pipeline supports our sustainable growth from FY25 and includes approximately 30 programs with transformative or curative potential. In Q2 FY21, we announced a geographically-focused exclusive collaboration and license agreement with JCR Pharmaceuticals to commercialize pabinafusp alfa (JR-141) for the treatment of the somatic and neuronopathic manifestations of Hunter syndrome. In addition, we added TAK-105 for nausea and vomiting to our Wave 2 pipeline. We also announced our intent to acquire GammaDelta Therapeutics to accelerate the development of allogeneic gamma delta T-cell therapies with the intention to finalize the deal in Q1 FY22. Closing of the transaction is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 in the U.S.

BENEFITS OF OUR STRATEGIC APPROACH

- Targets with great therapeutic value and nimble, less costly development programs
- Faster tracks to registration
- Enhanced patent protection and marketing rights
- Partner programs to de-risk investments by Takeda
- Approximately 1/2 of pipeline with orphan drug designation

Wave 1: Delivering Near-Term Growth Through FY24

14
global brands delivering for patients today

25+
pivotal studies underway or in development

25+
additional launches for the global brands through FY24

15+
transformative medicines potentially delivered to patients in China by FY25[2]

Global Growth Brand Expansions

Our 14 global growth brands continue to generate significant opportunities through new indications and geographic expansion. For our 14 global brands, we are targeting the following extensions through FY24[3]:

FY21	FY22	FY23		FY24
TAKHZYRO ☑ *HAE; JP*	**ALUNBRIG** *1L ALK+ NSCLC; CN* *2L ALK+ NSCLC; CN*	**ALOFISEL** *CPF; US*	**NINLARO** *NDMM nSCT; EU, US* *NDMM SCT; EU, US*	**ENTYVIO SC** *CD/UC Needle free; EU*
NINLARO ☑ *NDMM nSCT; JP*	**ENTYVIO** *AB-refract pouchitis; EU*	**ALUNBRIG** *H2H Alectinib NSCLC; US, EU*	**TAKHZYRO** *BMA; US* *HAE Peds; EU, US*	**GATTEX** *SBS; CN*
ALOFISEL ☑ *CPF; JP*	**HYQVIA** *Pediatric PID; US* *HyHub Device; EU, US*	**ADYNOVATE** *HemA; CN*	**HYQVIA** *CIDP; EU, US* *MMN; EU* *HyHub Duo Device; EU,US*	**NINLARO** *NDMM nSCT; EM* *NDMM nSCT (CN); CN*
GATTEX ☑ *SBS; JP*		**ENTYVIO SC** *UC/CD SC; JP, US*[4] *CD/UC Needle free; US*	**Gammagard Liquid** *CIDP; US*	**HYQVIA** *PID, SID; JP*
			CUVITRU *PID, SID; JP*	

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First-in-Class & Best-in-Class NMEs with Near-Term Milestones

The main driver for new product launches in the near term are our Wave 1 NMEs, which represent several potential best-in-class / first-in-class therapies, and two regional COVID-19 vaccines.

TARGET APPROVAL[5] →	FY21	FY22	FY23	FY24
ONCOLOGY	**EXKIVITY**[6] ☑ *2L NSCLC with EGFR exon 20 insertion mutation*		**EXKIVITY**[6] *1L NSCLC with EGFR exon 20 insertion mutation*	
RARE GENETICS & HEMATOLOGY	**LIVTENCITY**[6] ☑ *R/R CMV infect. in transplant*	**TAK-609**[7] *Hunter CNS (IT)*	**LIVTENCITY**[6] *1L CMV infect. in HSCT* **TAK-755** *cTTP*	**TAK-611** *MLD (IT)*
NEUROSCIENCE			**soticlestat** *DS* **soticlestat** *LGS*	
GASTRO-ENTEROLOGY	**Eohilia**[9] *EoE* *Received CRL*			
VACCINES	**TAK-019** *Novavax COVID-19 vaccine (JP)* **COVID-19 Vaccine** ☑ *Moderna intramuscular injection (JP)*	**TAK-003** *Dengue vaccine*		

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Wave 2: Driving Innovation and Supporting Sustained Growth (FY25 & Beyond)

Our Wave 2 pipeline contains approximately 30 NMEs, many with the potential to become curative, life-saving treatments in the next decade. Momentum of our Wave 2 pipeline is the result of our investment in foundational capabilities in cell and gene therapies and data sciences. These investments, combined with our unparalleled expertise, enable Takeda to leverage best practices from one modality to build robust capabilities in new areas.

TARGET APPROVAL[1] →	FY25 & BEYOND				
ONCOLOGY	**modakafusp alfa** *R/R MM*	**TAK-007** *CD19+ hematologic malignancies*	**TAK-676** *Solid tumors*	**TAK-102** *Multiple cancers*	
	subasumstat *Multiple cancers*	**TAK-605** *Multiple cancers*	**TAK-186** *EGFR solid tumor*	**TAK-940** *CD19+ hematologic malignancies*	
RARE GENETICS & HEMATOLOGY	**pabinafusp alfa**[10] *Hunter syndrome*	**mezagitamab** *MG, ITP*			
	TAK-755 *iTTP, SCD*	**TAK-607** *Complications of prematurity*			
NEUROSCIENCE	**orexin 2R-ag** *TAK-861/994*[11] *NT1, NT2, IH, other*	**TAK-653**[12] *Inadequate resp. in MDD*	**TAK-341** *Parkinson's disease*		
	orexin 2R-ag *TAK-925* *Hospital setting*	**TAK-041**[12] *Anhedonia in MDD*	**TAK-071** *Parkinson's disease*		
GASTRO-ENTEROLOGY	**TAK-999** *AATD liver disease*	**TAK-951** *Nausea & vomiting*	**TAK-105** *Nausea & vomiting*	**TAK-101** *Celiac disease*	**sibofimloc** *Crohn's disease (post-op and ileitis)*
	TAK-906 *Gastroparesis*	**TAK-954** *POGD*	**TAK-510** *Nausea & vomiting*	**TAK-062** *Celiac disease*	**TAK-039** *Hepatic encephalopathy*
VACCINES	**TAK-426** *Zika vaccine*				

1. Certain Wave 2 programs may be accelerated into Wave 1 depending on future data read outs.
2. Of the 15+ new medicines, six represent our global brands: Entyvio®, Alunbrig®, Ninlaro®, Vpriv®, Takhzyro®, Adynovate®.
3. Table only shows selected R&D milestones and is not comprehensive.
4. In active discussions with the FDA. Timelines under review; potential approval anticipated FY23.
5. Potential approval dates depend on data read outs; some Wave 1 target approval dates assume accelerated approval.
6. EXKIVITY (brand) – mobocertinib (generic), LIVTENCITY (brand) – maribavir (generic)
7. Filing of TAK-609 is subject to feedback from regulatory agencies on the ongoing extension trial and may change.
8. TAK-994 approval timelines under review.
9. Takeda has received a Complete Response Letter (CRL) from the FDA, and no longer expects approval in FY2021. Takeda is assessing the details of the CRL.
10. Partnership with JCR Pharmaceuticals.
11. TAK-994 timeline under evaluation.
12. 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 as of January 10, 2022. For glossary of disease abbreviations please refer to the following page.

Our rich history guides us, and the future energizes us. We are proud of our more than **200 years of the scientific innovation and R&D** that has helped us advance our goal to bring better health for people and a brighter future for the world.

Glossary of Abbreviations

1L	first line
2L	second line
AATD	alpha-1 antitrypsin deficiency
ALK	anaplastic lymphoma kinase
BMA	bradykinin mediated angioedema
CD	Crohn's disease
CHMP	Committee for Medicinal Products for Human Use
CIDP	chronic inflammatory demyelinating polyradiculoneuropathy
COVID-19	coronavirus disease 2019
CMV	cytomegalovirus
CN	China
CNS	central nervous system
CPF	complex perianal fistula
CRL	complete response letter
cTTP	congenital thrombotic thrombocytopenic purpura
DS	Dravet syndrome
EGFR	epidermal growth factor receptor
EM	emerging markets
EoE	eosinophilic esophagitis
EU	European Union
FY	fiscal year
H2H	head to head
HAE	hereditary angioedema
HemA	hemophilia A
HPT	hypothyroidism
HSCT	hematopoietic stem cell transplants
HSR	Hart-Scott-Rodino
IH	idiopathic hypersomnia
IT	intrathecal
ITP	idiopathic thrombocytopenic purpura
iTTP	immune thrombotic thrombocytopenic purpura
JP	Japan
LGS	Lennox-Gastaut syndrome
MDD	major depressive disorder
MG	myasthenia gravis
MHLW	Ministry of Health, Labour and Welfare
MLD	metachromatic leukodystrophy
MM	multiple myeloma
NDMM	newly diagnosed multiple myeloma
NME	new molecular entity
NSCLC	non-small cell lung cancer
nSCT	non stem cell transplant
NT1 or NT2	narcolepsy type 1 or 2
Orexin2R-ag	orexin 2 receptor agonist
PDT	Plasma-Derived Therapies (business unit)
Peds	pediatric
PID	primary immunodeficiency
Post-op	post-operative
POGD	post-operative gastrointestinal dysfunction
R&D	research and development
RNA	ribonucleic acid
R/R	relapse/refractory
SBS	short bowel syndrome
SC	subcutaneous formulation
SCD	sickle cell disease
SCT	stem cell transplant
SID	secondary immunodeficiency
T1	type 1
UC	ulcerative colitis
US	United States

Forward-Looking Statements

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