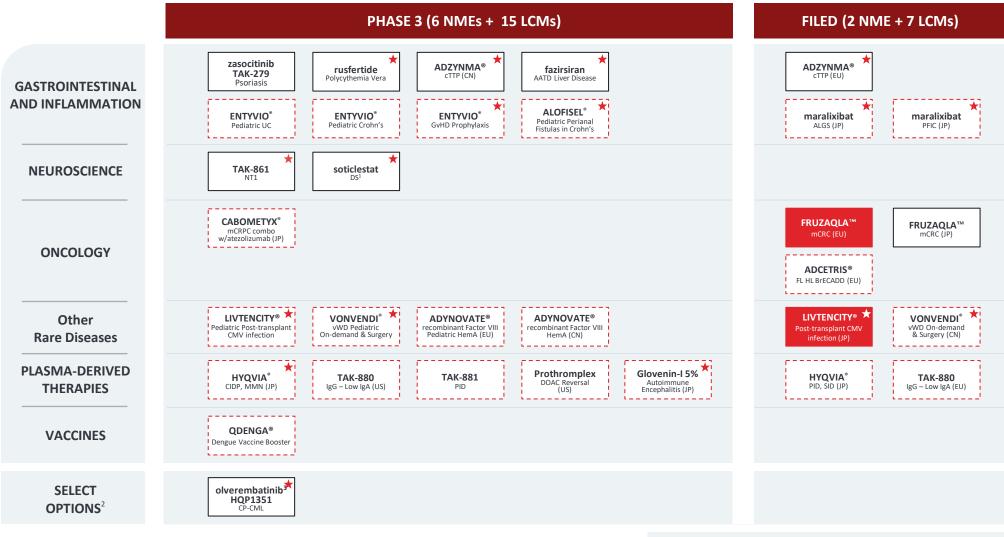
# **Consolidated Development Pipeline by Phase**





<sup>1.</sup> Soticlestat DS totality of Phase 3 data suggests potential clinically meaningful benefit despite missing primary endpoint. Next step discuss potential filing with FDA.

APPROVED

NME

LCM

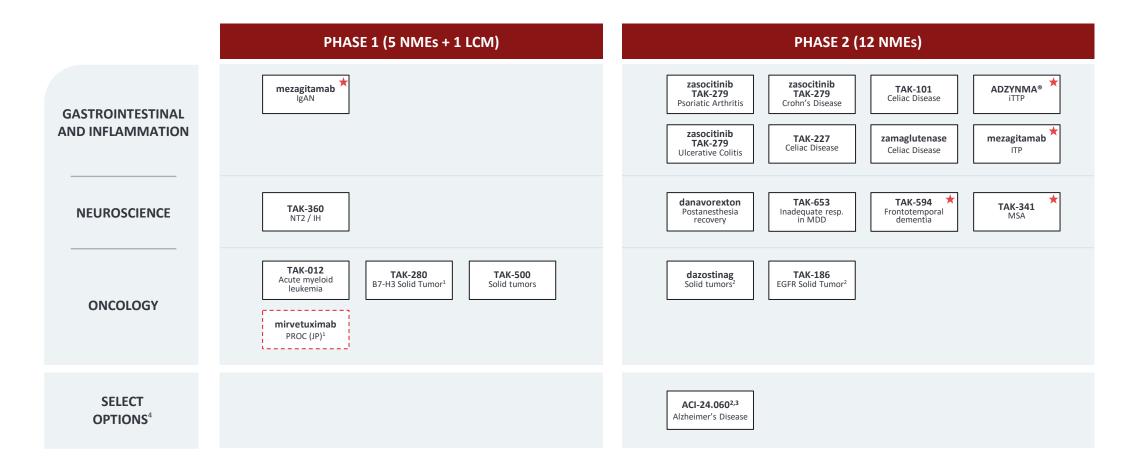
Orphan Drug Designation potential (in any region / indication for a given asset)

<sup>2.</sup> Select options: Other selected assets that Takeda holds contractual rights to potentially clinically develop and/or commercialize in the future.

<sup>3.</sup> Olverembatinib/HQP1351 is included for reference only. Ascentage Pharma retains ownership of this asset and is solely responsible for its clinical development prior to Takeda's potential exercise of its option to exclusively license certain rights, which is subject to customary conditions including antitrust approval.

# **Consolidated Development Pipeline by Phase**





- 1. Currently in phase 1 of a phase 1/2 trial
- 2. Currently in phase 2 of a phase 1/2 trial
- ACI-24.060 is included for reference only. AC Immune retains ownership of this asset and is solely responsible for its
  clinical development prior to Takeda's potential exercise of its option to exclusively license certain rights, which is
  subject to customary conditions including antitrust approval.
- Select options: Other selected assets that Takeda holds contractual rights to potentially clinically develop and/or commercialize in the future.

★ Orphan Drug Designation potential (in any region / indication for a given asset)

NME

LCM

All timelines are approximate estimates as of July 31st, 2024, are subject to change and are subject to clinical and regulatory success. Table is not comprehensive. For full glossary of abbreviations please refer to appendix.

# **Glossary of Abbreviations**



#### Regional Abbreviations:

CN: China; EU: Europe; JP: Japan; UK: United Kingdom; U.S.: United States of America

United State	s of America
AATD	α1-antitrypsin deficiency
AATD LD	α1-antitrypsin deficiency associated liver disease
ADAMTS13	a disintegrin-like and metalloproteinase with a thrombospondin type 1 motifs 13
ALGS	Alagille syndrome
ALK	anaplastic lymphoma kinase
ALL	acute lymphocytic leukemia
AVA	Advanced Vial Access
BID	bis in die, twice a day
BLA	biologics license application
BTD	breakthrough therapy designation
CAR NK	chimeric antigen receptor natural killer cell
СНМР	Committee for Medicinal Products for Human Use
CIDP	chronic inflammatory demyelinating polyradiculoneuropathy
CML	chronic myeloid leukemia
CMV	cytomegalovirus
CP-CML	chronic-phase chronic myeloid leukemia
CPF	complex perianal fistulas
CRC	colorectal cancer
CRL	complete response letter
CRPC	castrate-resistant prostate cancer
cTTP	congenital thrombotic thrombocytopenic purpura
DOAC	direct oral anti-coagulation
DS	Dravet syndrome

EGFR	epidermal growth factor receptor
EMA	European Medicines Agency
ESS	Epworth Sleepiness Scale
FDA	U.S. Food & Drug Administration
FL	front line
FSI	first subject in
FY	fiscal year
GI	gastrointestinal
GvHD	graft versus host disease
Н2Н	head-to-head
HAE	hereditary angioedema
HemA	hemophilia A
HL	Hodgkin lymphoma
IBD	inflammatory bowel disease
IgA	immunoglobulin A
IgAN	immunoglobulin A nephropathy
IgG	immunoglobulin G
IH	idiopathic hypersomnia
IND	investigational new drug
INN	international non-proprietary name
ISTH	International Society on Thrombosis and Haemostasis
ITP	immune thrombocytopenia
iTTP	immune thrombotic thrombocytopenic purpura
IV	intravenous
JAK	Janus kinase
LCM	lifecycle management

LGS	Lennox-Gastaut syndrome
LS	least square
LTE	long-term extension
mCRC	metastatic colorectal cancer
mCRPC	metastatic castrate-resistant prostate cancer
MDD	major depressive disorder
MG	myasthenia gravis
MM	multiple myeloma
MMN	multifocal motor neuropathy
MSA	multiple system atrophy
MWT	maintenance of wakefulness test
ND	newly diagnosed
NDA	new drug application
NEJM	New England Journal of Medicine
NK	natural killer
NME	new molecular entity
NMPA	(China's) National Medical Products Administration
NSCLC	non-small cell lung cancer
NT1 or 2	narcolepsy type 1 or 2
PASI	psoriasis area and severity index
PFIC	progressive familial intrahepatic cholestasis
Ph+ ALL	Philadelphia chromosome-positive acute lymphoblastic leukemia
PID	primary immunodeficiency
PK	pharmacokinetics
PMDA	Japan's Pharmaceuticals and Medical Devices Agency

PNS	Peripheral Nerve Society
POC	proof of concept
PR	platelet response
PRIME	Priority medicines scheme by EMA
PROC	platinum-resistant ovarian cancer
QD	quaque die, every day
QOL	quality of life
R/R	relapsed/refractory
RTU	ready to use
sc	subcutaneous formulation
SCD	sickle cell disease
SCT	stem cell transplant
SEM	standard error of the mean
SID	secondary immunodeficiency
SLE	systemic lupus erythematosus
soc	standard of care
TEAE	treatment emergent adverse event
TKI	tyrosine kinase inhibitor
TTP	thrombotic thrombocytopenic purpura
TYK2	tyrosine kinase 2
UC	ulcerative colitis
VEGFR	vascular endothelial growth factor receptors
vWD	von Willebrand disease
WCR	weekly cataplexy rate
ww	Worldwide

## 1. Pipeline

#### I. Clinical Development Activities

- Except as otherwise noted, the following tables list the pipeline assets that we (i) are clinically developing ourselves or with partners, or (ii) hold contractual rights to potentially clinically develop and/or commercialize in the future, as of July 31, 2024 (the date of our earnings release for the first quarter ended June 30, 2024), but may not be comprehensive. The assets in our pipeline are in various stages of development, and the contents of the pipeline may change as therapeutic candidates currently under development drop out and new therapeutic candidates are introduced. Whether the therapeutic candidates listed below are ever successfully released as products depends on various factors, including the results of pre-clinical and clinical trials, market conditions for various drugs and regulatory approvals.
- This table primarily shows the indications for which we are actively pursuing regulatory approval and those regulatory approvals granted during fiscal year 2024. We are also conducting additional studies of certain assets to examine their potential for use in further indications and in additional formulations.
- The listings in this table are limited to the U.S., EU and Japan and China, but we are also actively conducting development activities in other regions, including in Emerging Markets. Country/region column denotes where a pivotal clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China. 'Global' refers to U.S., EU, Japan and China.
- Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU,
   Japan or China and Takeda has commercialization rights for such asset.
- Stage-ups are recognized in the table upon achievement of First Subject In, unless otherwise specified.
- Modality of our pipeline assets in the following table is classified into either of the following categories: 'small molecule', 'peptide/oligonucleotide', 'cell and gene therapy' or 'biologic and other.'

#### **Gastrointestinal and Inflammation Pipeline**

Development code <generic name=""> Brand name (country/region)</generic>	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
			Crohn's disease (subcutaneous formulation)	U.S.	Approved (Apr 2024)
MLN0002 <vedolizumab> ENTYVIO (Global)</vedolizumab>	<ul> <li><vedolizumab></vedolizumab></li> <li>ENTYVIO</li> <li>Humanized monoclonal antibody against α4β7</li> <li>integrin (injection)</li> </ul>	Biologic and other	Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation (intravenous formulation)	EU Japan	P-III P-III
			Pediatrics Study (intravenous formulation for ulcerative colitis, Crohn's disease)	Global	P-III
TAK-755¹ <apadamtase alfa="" cinaxadamtase=""></apadamtase>	replacement therapy	Biologic and other	Congenital Thrombotic Thrombocytopenic Purpura	EU China	Filed (May 2023) <sup>2</sup> P-III
ADZYNMA (U.S., Japan)	(injection)	other	Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II (b) P-II (b)
TAK-625 <sup>3</sup>	IBAT inhibitor (oral)	Small	Alagille syndrome	Japan	Filed (Jun 2024)
<maralixibat></maralixibat>	IBAI IIIIIIIIII (01ai)	molecule	Progressive Familial Intrahepatic Cholestasis	Japan	Filed (Jun 2024)
Cx601 <darvadstrocel> ALOFISEL (EU, Japan)</darvadstrocel>	A suspension of allogeneic expanded adipose- derived stem cells (injection)	Biologic and other	Pediatric indication for refractory complex perianal fistulas in patients with Crohn's disease	EU Japan	P-III P-III
TAK-999 <sup>4</sup> <fazirsiran></fazirsiran>	GalNAc based RNA interference (RNAi) (injection)	Peptide/ Oligo- nucleotide	Alpha-1 antitrypsin-deficiency associated liver disease	U.S. EU	P-III P-III
TAK-121 <sup>5</sup> <rusfertide></rusfertide>	Hepcidin mimetic peptide (injection)	Peptide/oligo nucleotide	Polycythemia vera	U.S.	P-III

		Small molecule	Psoriasis	Global	P-III
TAK-279	TYK2 inhibitor (oral)		Psoriatic Arthritis	-	P-II (b)
<zasocitinib></zasocitinib>	<zasocitinib></zasocitinib>		Crohn's disease	-	P-II (b)
			Ulcerative colitis	-	P-II (b)
TAK-227/ZED1227 <sup>6</sup>	Transglutaminase 2 inhibitor (oral)	Small molecule	Celiac disease	-	P-II (b)
TAK-062 <zamaglutenase></zamaglutenase>	Glutenase (oral)	Biologic and other	Celiac disease	-	P-II
TAK-101 <sup>7</sup>	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II
TAK-079	Anti-CD38 monoclonal	Biologic	Immune thrombocytopenia	-	P-II
<mezagitamab></mezagitamab>	antibody (injection)	and other	Immunoglobulin A nephropathy	-	P-I

- 1. Partnership with KM Biologics.
- 2. In May 2024, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) recommended the approval, under exceptional circumstances, of TAK-755 for the treatment of ADAMTS13 deficiency in children and adult patients with cTTP.
- 3. Partnership with Mirum Pharmaceuticals.
- 4. Partnership with Arrowhead Pharmaceuticals
- $5. \ \ Partnership \ with \ Protagonist \ The rapeutics. \ Protagonist \ leads \ development$
- 6. Partnership with Zedira and Dr. Falk Pharma. Dr. Falk Pharma leads development.
- 7. Partnership with COUR Pharmaceuticals.

Additions since FY2023 Q4: None Removals since FY2023 Q4: None

### **Neuroscience Pipeline**

Development code <generic name=""> Brand name (country/region)</generic>	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-935 <soticlestat></soticlestat>	CH24H inhibitor (oral)	Small molecule	Dravet syndrome <sup>1</sup>	Global	P-III
TAK-861	Orexin 2R agonist (oral)	Small molecule	Narcolepsy type 1	Global	P-III
TAK-653/ NBI-1065845 <sup>2</sup>	AMPA receptor potentiator (oral)	Small molecule	Inadequate response to treatment in major depressive disorder (MDD)	-	P-II
TAK-341/MEDI1341 <sup>3</sup>	Alpha-synuclein antibody (injection)	Biologic and other	Multiple System Atrophy (MSA)	-	P-II
TAK-594/DNL5934	Brain-penetrant progranulin fusion protein (injection)	Biologic and other	Frontotemporal dementia	-	P-II
TAK-925	Orexin 2R agonist	Small	Postanesthesia Recovery	-	P-II
<danavorexton></danavorexton>	(injection)	molecule	Narcolepsy	-	P-I
TAK-360	Orexin 2R agonist (oral)	Small molecule	Narcolepsy type 2 / Idiopathic hypersomnia	-	P-I

<sup>1.</sup> Soticlestat Dravet syndrome totality of Phase 3 data suggests potential clinically meaningful benefit despite missing primary endpoint. Next step discuss potential filing with FDA.

- 2. Partnership with Neurocrine Biosciences. Neurocrine leads development.
- 3. Partnership with AstraZeneca.
- 4. Partnership with Denali Therapeutics. Denali leads development.

Additions since FY2023 Q4: None

Removals since FY2023 Q4: TAK-935 for Lennox-Gastaut syndrome (Global, P-III, discontinued)

## **Oncology Pipeline**

Development code <generic name=""> Brand name (country/region)</generic>	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-113¹ <fruquintinib> FRUZAQLA (U.S., EU)</fruquintinib>	VEGFR inhibitor (oral)	Small molecule	Previously treated metastatic Colorectal Cancer (mCRC)	EU Japan	Approved (Jun 2024) Filed (Sep 2023)
SGN-35 <sup>2</sup>                               	CD30 monoclonal antibody-drug conjugate (injection)	Biologic and other	Front line Hodgkin's lymphoma – BrECADD regimen (brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone) <sup>3</sup>	EU	Filed (Apr 2024)
<cabozantinib><sup>4</sup> CABOMETYX (Japan)</cabozantinib>	Multi-targeted kinase inhibitor (oral)	Small molecule	Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab <sup>5</sup>	Japan	P-III
TAK-676 <dazostinag></dazostinag>	STING agonist (injection)	Small molecule	Solid tumors	-	P-II
TAK-186	T Cell Engager (injection)	Biologic and other	EGFR expressing solid tumors	-	P-II
TAK-500	STING agonist antibody drug conjugate (injection)	Biologic and other	Solid tumors	-	P-I
TAK-280	T Cell Engager (injection)	Biologic and other	B7-H3 expressing solid tumors	-	P-I
TAK-012	Variable delta 1 (Vδ1) gamma delta (γδ) T cells (injection)	Cell and gene therapy	Relapsed/refractory Acute Myeloid Leukemia	-	P-I
TAK-853 <sup>6</sup> <mirvetuximab soravtansine-gynx&gt;</mirvetuximab 	Antibody-drug conjugate targeting folate receptor $\alpha$ (FR $\alpha$ ) (injection)	Biologic	Platinum-resistant ovarian cancer	Japan	P-I

- 1. Partnership with HUTCHMED
- 2. Partnership with Pfizer Inc.
- 3. Submission based on data from German Hodgkin Study Group HD21 trial.
- 4. Partnership with Exelixis, Inc.
- 5. Partnership with Chugai Pharmaceutical. Takeda operates P-III development.
- 6. Partnership with AbbVie.

Additions since FY2023 Q4: TAK-853 for platinum-resistant ovarian cancer (Japan, P-I)
Removals since FY2023 Q4: ICLUSIG Pediatric indication for Philadelphia chromosome positive Acute Lymphoblastic Leukemia (P-I, discontinued)

## Other Rare Diseases Pipeline

Development code <generic name=""> Brand name (country/region)</generic>	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-620¹ <maribavir></maribavir>		Small molecule	Treatment of refractory Post Transplantation (Including HSCT) CMV Infection/disease	Japan	Approved (Jun 2024)
1 7		molecule	Treatment of children and teenage transplant recipients with CMV infection	EU	P-III
TAK-577 VONVENDI	I von Willebrand factor	Biologic	Adult on-demand and surgery treatment of von Willebrand disease	China	Filed (Jan 2023)
(U.S., Japan)  VEYVONDI (EU)	(injection)	and other	Pediatric on-demand and surgery treatment of von Willebrand disease	Global	P-III
TAK-660 ADYNOVATE	ADYNOVATE [recombinant], (U.S., Japan) PEGylated	Biologic	Pediatric Hemophilia A	EU	P-III
(U.S., Japan) ADYNOVI (EU)		and other	Hemophilia A	China	P-III

1. Partnership with GSK

Additions since FY2023 Q4: None Removals since FY2023 Q4: None

**Plasma-Derived Therapies Pipeline** 

	Therapies ripein			1	I
Development code <generic name=""> Brand name (country/region)</generic>	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-771 <sup>1</sup> <ig 10%<br="" infusion="">(Human) w/</ig>	Immunoglobulin (IgG) + recombinant	Biologic and	Primary Immunodeficiencies and Secondary Immunodeficiencies	Japan	Filed (Feb 2024)
Recombinant Human Hyaluronidase> HYQVIA (U.S., EU)	hyaluronidase replacement therapy (subcutaneous infusion)	other	Chronic inflammatory demyelinating polyradiculoneuropathy and Multifocal Motor Neuropathy	Japan	P-III
TAK-880 <10% IVIG (Low IgA)>	Immunoglobulin (10%) [human] (injection) (Low IgA)	Biologic and other	Primary Immunodeficiencies and Multifocal Motor Neuropathy	EU U.S.	Filed (Mar 2024) Filing in preparation
TAK-330 PROTHROMPLEX TOTAL (EU)	Four-factor prothrombin complex concentrate [human] (injection)	Biologic and other	Coagulation Disorder, Direct Oral Anticoagulants (DOAC) reversal in surgical situations	U.S.	P-III
TAK-961 <5% IVIG> GLOVENIN-I (Japan)	Immunoglobulin (5%) [human] (injection)	Biologic and other	Autoimmune Encephalitis (AE)	Japan	P-III
TAK-881 <facilitated 20%<br="">SCIG&gt;</facilitated>	Immunoglobulin (20%) [human] + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Primary Immunodeficiencies	U.S. EU	P-III P-III

<sup>1.</sup> Partnership with Halozyme

Additions since FY2023 Q4: None Removals since FY2023 Q4: None

## **Vaccines Pipeline**

Development code Brand name (country/region)	Type of vaccine (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-003 QDENGA (Global)	Tetravalent dengue vaccine (injection)		For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older (booster extension)	-	P-III

Additions since FY2023 Q4: None

Removals since FY2023 Q4: TAK-003 for the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older (US, filing withdrawn).