

# Consolidated Development Pipeline by Phase



- GASTROINTESTINAL AND INFLAMMATION
- NEUROSCIENCE
- ONCOLOGY
- Other Rare Diseases
- PLASMA-DERIVED THERAPIES
- VACCINES

PHASE 3 (5 NMEs + 17 LCMs)				
<p><b>zasocitinib</b> TAK-279 Psoriasis</p>	<p><b>rusfertide</b> ★ Polycythemia Vera</p>	<p><b>ENTYVIO</b>® Pediatric UC</p>	<p><b>ALOFISEL</b>® ★ Pediatric Perianal Fistulas in Crohn's</p>	<p><b>maralixibat</b> ★ ALGS (JP)</p>
<p><b>ADZYNMA</b>® ★ cTTP (CN)</p>	<p><b>fazirsiran</b> ★ AATD Liver Disease</p>	<p><b>ENTYVIO</b>® Pediatric Crohn's</p>	<p><b>ENTYVIO</b>® ★ GvHD Prophylaxis</p>	<p><b>maralixibat</b> ★ PFIC (JP)</p>
<p><b>soticlestat</b> ★ DS</p>	<p><b>soticlestat</b> ★ LGS</p>			
<p><b>CABOMETYX</b>® mCRC combo w/atezolizumab (JP)</p>				
<p><b>LIVTENCITY</b>® ★ Pediatric Post-transplant CMV infection</p>	<p><b>VONVENDI</b>® ★ vWD Pediatric On-demand &amp; Surgery</p>	<p><b>ADYNOVATE</b>® recombinant Factor VIII Pediatric Hema (EU)</p>	<p><b>ADYNOVATE</b>® recombinant Factor VIII Hema (CN)</p>	
<p><b>HYQVIA</b>® ★ CIDP, MMN (JP)</p>	<p><b>TAK-880</b> IgG – Low IgA (US)</p>	<p><b>TAK-881</b> PID</p>	<p><b>Prothromplex</b> DOAC Reversal (US)</p>	<p><b>Glovenin-I</b> ★ Autoimmune Encephalitis (JP)</p>
<p><b>QDENG A</b>® Dengue Vaccine Booster</p>				

FILED (3 NME + 23 LCMs)			
<p><b>ADZYNMA</b>® ★ cTTP (US)</p>	<p><b>ADZYNMA</b>® ★ cTTP (EU)</p>	<p><b>ENTYVIO</b>® SC UC (US)</p>	<p><b>VOCINTI</b>® <i>H. Pylori</i> (CN)</p>
<p><b>EOHILIA</b> ★ Eosinophilic esophagitis (US)</p>	<p><b>ADZYNMA</b>® ★ cTTP (JP)</p>	<p><b>ENTYVIO</b>® SC Crohn's (US, JP)</p>	<p><b>REVESTIVE</b>® Short Bowel Syndrome (CN)</p>
<p><b>FRUZAQLA</b>™ mCRC (US)</p>	<p><b>FRUZAQLA</b>™ mCRC (JP)</p>	<p><b>ADCETRIS</b>® FL HL Stage III (EU)</p>	<p><b>ADCETRIS</b>® FL HL BrECADD (EU)</p>
<p><b>FRUZAQLA</b>™ mCRC (EU)</p>	<p><b>ICLUSIG</b>® 1L Ph+ ALL (US)</p>	<p><b>ADCETRIS</b>® ★ R/R CTCL (JP)</p>	
<p><b>LIVTENCITY</b>® ★ Post-transplant CMV infection (JP)</p>	<p><b>LIVTENCITY</b>® ★ R/R Post-transplant CMV infection (CN)</p>	<p><b>TAKHZYRO</b>® ★ Pediatric HAE (EU)</p>	<p><b>OBIZUR</b>® ★ Recomb antihemophilic factor porcine (JP)</p>
<p><b>OBIZUR</b>® ★ Recomb antihemophilic factor porcine (CN)</p>	<p><b>VEYVONDI</b>® ★ vWD Adult Prophylaxis (EU)</p>	<p><b>VONVENDI</b>® ★ vWD On-demand &amp; Surgery (CN)</p>	
<p><b>HYQVIA</b>® ★ CIDP (US, EU)</p>	<p><b>HYQVIA</b>® ★ Pediatric PID (US)</p>	<p><b>CUVITRU</b>® PID, SID (JP), SID (EU)</p>	<p><b>CEPROTIN</b>® SCPCD (JP)</p>
<p><b>HYQVIA</b>® PID, SID (JP)</p>	<p><b>GAMMAGARD LIQUID</b>® CIDP (US)</p>	<p><b>TAK-880</b> IgG – Low IgA (EU)</p>	<p><b>FEIBA</b>® STAR Extension (US, EU)</p>

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

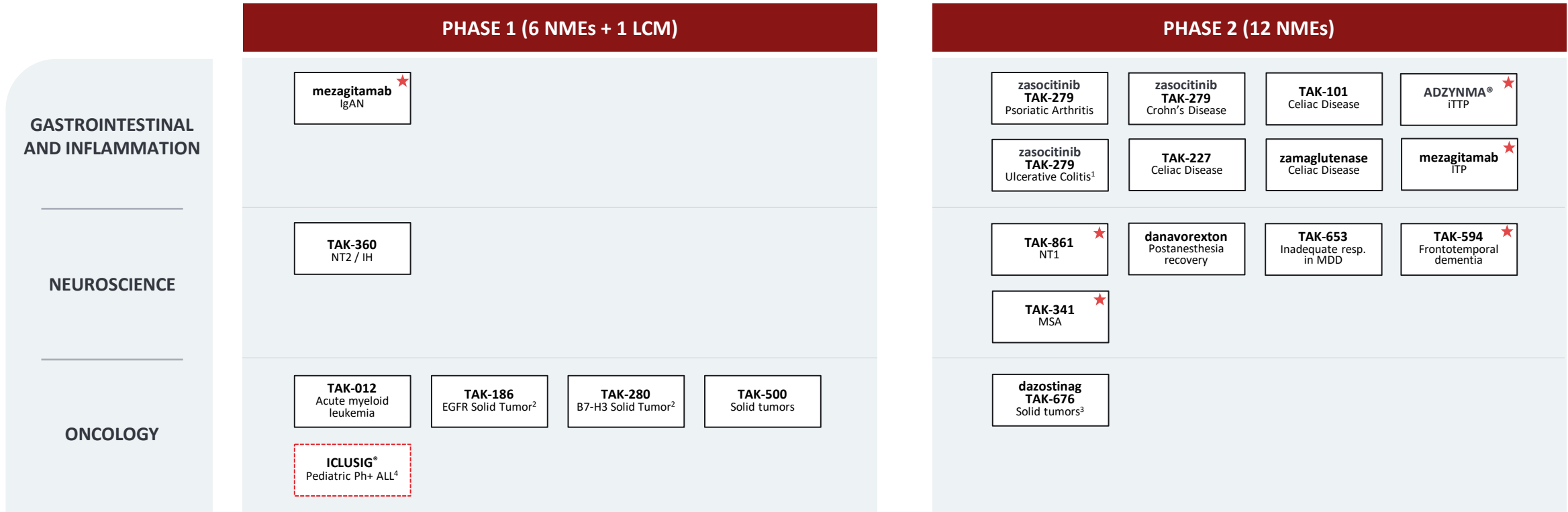
APPROVED

NME

LCM

All timelines are approximate estimates as of May 9<sup>th</sup>, 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.

# Consolidated Development Pipeline by Phase



1. Study actively recruiting
2. Currently in phase 1 of a phase 1/2 trial
3. Currently in phase 2 of a phase 1/2 trial
4. ICLUSIG pediatric Ph+ ALL enrolment has been closed

All timelines are approximate estimates as of May 9<sup>th</sup>, 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.

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

NME

LCM

# Glossary of Abbreviations



## Regional Abbreviations:

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

<b>AAD</b>	American Academy of Dermatology
<b>AATD</b>	α1-antitrypsin deficiency
<b>AATD LD</b>	α1-antitrypsin deficiency associated liver disease
<b>ACR</b>	American College of Rheumatology
<b>ADAMTS13</b>	a disintegrin-like and metalloproteinase with a thrombospondin type 1 motifs 13
<b>ADHD</b>	attention deficit hyperactivity disorder
<b>ALGS</b>	Alagille syndrome
<b>ALK</b>	anaplastic lymphoma kinase
<b>ALL</b>	acute lymphocytic leukemia
<b>AVA</b>	Advanced Vial Access
<b>BID</b>	bis in die, twice a day
<b>BLA</b>	biologics license application
<b>BTD</b>	breakthrough therapy designation
<b>CAR NK</b>	chimeric antigen receptor natural killer cell
<b>CHMP</b>	Committee for Medicinal Products for Human Use
<b>CIDP</b>	chronic inflammatory demyelinating polyradiculoneuropathy
<b>CML</b>	chronic myeloid leukemia
<b>CMV</b>	cytomegalovirus
<b>CPF</b>	complex perianal fistulas
<b>CRC</b>	colorectal cancer
<b>CRL</b>	complete response letter
<b>CRPC</b>	castrate-resistant prostate cancer
<b>CTCL</b>	cutaneous T-cell lymphoma
<b>cTTP</b>	congenital thrombotic thrombocytopenic purpura
<b>DOAC</b>	direct oral anti-coagulation
<b>DS</b>	Dravet syndrome

<b>DSQ</b>	Dysphagia Symptom Questionnaire
<b>EGFR</b>	epidermal growth factor receptor
<b>EMA</b>	European Medicines Agency
<b>EoE</b>	eosinophilic esophagitis
<b>ESS</b>	Epworth Sleepiness Scale
<b>FDA</b>	U.S. Food & Drug Administration
<b>FL</b>	front line
<b>FSI</b>	first subject in
<b>FY</b>	fiscal year
<b>GI</b>	gastrointestinal
<b>GvHD</b>	graft versus host disease
<b>H2H</b>	head-to-head
<b>HAE</b>	hereditary angioedema
<b>HemA</b>	hemophilia A
<b>HL</b>	Hodgkin lymphoma
<b>IARS</b>	International Anesthesia Research Society
<b>IBD</b>	inflammatory bowel disease
<b>IgA</b>	immunoglobulin A
<b>IgAN</b>	immunoglobulin A nephropathy
<b>IgG</b>	immunoglobulin G
<b>IH</b>	idiopathic hypersomnia
<b>IND</b>	investigational new drug
<b>INN</b>	international non-proprietary name
<b>IT</b>	intrathecal
<b>ITP</b>	immune thrombocytopenia
<b>iTTP</b>	immune thrombotic thrombocytopenic purpura
<b>IV</b>	intravenous
<b>JAK</b>	Janus kinase
<b>LCM</b>	lifecycle management

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

<b>PTCL-NOS</b>	peripheral T-cell lymphoma not otherwise specified
<b>QD</b>	quaque die, every day
<b>R/R</b>	relapsed/refractory
<b>RTU</b>	ready to use
<b>SC</b>	subcutaneous formulation
<b>SCD</b>	sickle cell disease
<b>SCPCD</b>	severe congenital protein C deficiency
<b>SCT</b>	stem cell transplant
<b>SID</b>	secondary immunodeficiency
<b>SLE</b>	systemic lupus erythematosus
<b>SOC</b>	standard of care
<b>TEAE</b>	treatment emergent adverse event
<b>TKI</b>	tyrosine kinase inhibitor
<b>TTP</b>	thrombotic thrombocytopenic purpura
<b>TYK2</b>	tyrosine kinase 2
<b>UC</b>	ulcerative colitis
<b>VEGFR</b>	vascular endothelial growth factor receptors
<b>vWD</b>	von Willebrand disease
<b>WCR</b>	weekly cataplexy rate
<b>WW</b>	Worldwide

# 1. Pipeline

## – Clinical Development Activities

- Except as otherwise noted, the following tables list the pipeline assets that we are clinically developing as of May 9, 2024 (the date of our earnings release for the fourth quarter ended March 31, 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 2023. 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)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
MLN0002 <vedolizumab> ENTYVIO (Global)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Biologic and other	Ulcerative colitis (subcutaneous formulation)	U.S.	Approved (Sep 2023)
			Crohn's disease (subcutaneous formulation)	Japan U.S.	Approved (Sep 2023) Approved (Apr 2024)*
			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-438 <vonoprazan> TAKECAB (Japan) VOCINTI (China)	Potassium-competitive acid blocker (oral)	Small molecule	Acid related diseases (adjunct to <i>Helicobacter pylori</i> eradication)	China	Approved (Nov 2023)
TAK-755 <sup>1</sup> <apadamtase alfa/ cinaxadamtase alfa> ADZYNMA (U.S.)	ADAMTS13 enzyme replacement therapy (injection)	Biologic and other	Congenital Thrombotic Thrombocytopenic Purpura	U.S. Japan EU China	Approved (Nov 2023) Approved (Mar 2024) Filed (May 2023) P-III
			Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II (b) P-II (b)
TAK-721 <budesonide> EOHILIA (U.S.)	Glucocorticosteroid (oral)	Small molecule	Eosinophilic esophagitis	U.S.	Approved (Feb 2024)
TAK-633 <teduglutide> GATTEX (U.S.) REVESTIVE (EU, Japan)	GLP-2 analogue (injection)	Peptide/oligo nucleotide	Short bowel syndrome	China	Approved (Feb 2024)

Cx601 <darvadstrocel> ALOFISEL (EU, Japan)	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>2</sup> <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-625 <sup>3</sup> <maralixibat>	IBAT inhibitor (oral)	Small molecule	Alagille syndrome	Japan	P-III
			Progressive Familial Intrahepatic Cholestasis	Japan	P-III
TAK-121 <sup>4</sup> <rusfertide>	Hepcidin mimetic peptide (injection)	Peptide/oligo nucleotide	Polycythemia vera	U.S.	P-III
TAK-279 <zasocitinib>	TYK2 inhibitor (oral)	Small molecule	Psoriasis	U.S. EU Japan	P-III P-III* P-III*
			Psoriatic Arthritis	-	P-II (b)
			Crohn's disease	-	P-II (b)
			Ulcerative colitis	-	P-II (b) <sup>5</sup>
TAK-227/ZED1227 <sup>6</sup>	Transglutaminase 2 inhibitor (oral)	Small molecule	Celiac disease	-	P-II (b)
TAK-062 <zamaglutinase>	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 <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Immune thrombocytopenia	-	P-II
			Immunoglobulin A nephropathy	-	P-I

- Partnership with KM Biologics.
- Partnership with Arrowhead Pharmaceuticals
- Partnership with Mirum Pharmaceuticals.
- Partnership with Protagonist Therapeutics. Protagonist leads development.
- Study actively recruiting.
- Partnership with Zedira and Dr. Falk Pharma.
- Partnership with COUR Pharmaceuticals.

\* Event occurred after the end of the Q4 reporting period: Update after April 1, 2024

Additions since FY2023 Q3: TAK-633 for Short bowel syndrome (China, approved)

TAK-121 for Polycythemia vera (U.S., P-III)

TAK-279 for Crohn's disease (P-II (b))

TAK-279 for Ulcerative colitis (P-II (b))

Removals since FY2023 Q3: TAK-755 for Sickle cell disease (U.S., P-I, deprioritized)

TAK-951 for nausea and vomiting (P-II, discontinued)

TAK-079 for Myasthenia gravis (P-II, deprioritized)

TAK-079 for Systemic lupus erythematosus (P-I/II, deprioritized)

TAK-647 for Metabolic dysfunction-associated steatohepatitis (MASH) (previously known as Nonalcoholic Steatohepatitis (NASH))

(P-I, discontinued)

## Neuroscience Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-935 <soticlestat>	CH24H inhibitor (oral)	Small molecule	Dravet syndrome	Global	P-III
			Lennox-Gastaut syndrome	Global	P-III
TAK-861	Orexin 2R agonist (oral)	Small molecule	Narcolepsy type 1	-	P-II (b)
TAK-653/ NBI-1065845 <sup>1</sup>	AMPA receptor potentiator (oral)	Small molecule	Inadequate response to treatment in major depressive disorder (MDD)	-	P-II
TAK-341/MEDI1341 <sup>2</sup>	Alpha-synuclein antibody (injection)	Biologic and other	Multiple System Atrophy (MSA)	-	P-II
TAK-594/DNL593 <sup>3</sup>	Brain-penetrant progranulin fusion protein (injection)	Biologic and other	Frontotemporal dementia	-	P-II
TAK-925 <danavorexton>	Orexin 2R agonist (injection)	Small molecule	Postanesthesia Recovery	-	P-II
			Narcolepsy	-	P-I
TAK-360	Orexin 2R agonist (oral)	Small molecule	Narcolepsy type 2 and Idiopathic hypersomnia	-	P-I*

1. Partnership with Neurocrine Biosciences. Neurocrine leads development.
2. Partnership with AstraZeneca. P-I Parkinson's disease study is completed.
3. Partnership with Denali Therapeutics. Denali leads development.

\* Event occurred after the end of the Q4 reporting period: Update after April 1, 2024

Additions since FY2023 Q3: TAK-360 for Narcolepsy type 2 and Idiopathic hypersomnia (P-I)

Removals since FY2023 Q3: TAK-861 for Narcolepsy type 2 (P-II (b), discontinued)

## Oncology Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
SGN-35 <sup>1</sup> <brentuximab vedotin> <i>ADCETRIS</i> (EU, Japan, China)	CD30 monoclonal antibody-drug conjugate (injection)	Biologic and other	Front line Hodgkin's lymphoma – Stage III	EU	Approved (Oct 2023)
			Relapsed or refractory cutaneous T-cell lymphoma	Japan	Approved (Nov 2023)
			Front line Hodgkin's lymphoma – BrECADD regimen (brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone) <sup>2</sup>	EU	Filed (Apr 2024)*
TAK-113 <sup>3</sup> <fruquintinib> <i>FRUZAQLA</i> (U.S.)	VEGFR inhibitor (oral)	Small molecule	Previously treated metastatic Colorectal Cancer (mCRC)	U.S. EU Japan	Approved (Nov 2023) Filed (Jun 2023) Filed (Sep 2023)
<ponatinib> <i>ICLUSIG</i> (U.S.)	BCR-ABL inhibitor (oral)	Small molecule	Front line Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	U.S.	Approved (Mar 2024)
			Pediatric indication for Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	-	P-I <sup>4</sup>
<cabozantinib> <sup>5</sup> <i>CABOMETYX</i> (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab <sup>6</sup>	Japan	P-III
TAK-676 <dazostinag>	STING agonist (injection)	Small molecule	Solid tumors	-	P-II
TAK-500	STING agonist antibody drug conjugate (injection)	Biologic and other	Solid tumors	-	P-I
TAK-186	T Cell Engager (injection)	Biologic and other	EGFR expressing 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

- Partnership with Pfizer Inc.
- Submission based on data from German Hodgkin Study Group HD21 trial.
- Partnership with HUTCHMED
- ICLUSIG pediatric Ph+ ALL enrolment has been closed.
- Partnership with Exelixis, Inc.
- Partnership with Chugai Pharmaceutical. Takeda operates P-III development.

\* Event occurred after the end of the Q4 reporting period: Update after April 1, 2024

Additions since FY2023 Q3: SGN-35 for Front line Hodgkin's lymphoma – BrECADD regimen (EU, Filed)

Removals since FY2023 Q3: SGN-35 for Front line Peripheral T-cell lymphoma-Not Otherwise Specified (PTCL-NOS) (EU, Filed, filing withdrawn)

MLN9708 for Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant (TOURMALINE-MM3) (U.S., EU, P-III, trial completed)

TAK-385 for Prostate cancer (Japan, China, P-III, development suspended due to regional business strategy)

TAK-981 for Multiple cancers (P-II, discontinued)

TAK-007 for Relapsed/refractory B cell malignancies (P-II, discontinued)

## Other Rare Diseases Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-620 <sup>1</sup> <maribavir> <i>LIVTENCITY</i> (U.S., EU)	Benzimidazole riboside inhibitor (oral)	Small molecule	Post-transplant cytomegalovirus (CMV) infection/disease resistant/refractory to (val) ganciclovir, cidofovir or foscarnet	China	Approved (Dec 2023)
			Treatment of CMV Infection/disease Post Transplantation (Including HSCT)	Japan	Filed (Nov 2023)
			Treatment of children and teenage transplant recipients with CMV infection	EU	P-III
TAK-743 <lanadelumab> <i>TAKHZYRO</i> (Global)	Plasma kallikrein inhibitor (injection)	Biologic and other	Pediatric Hereditary Angioedema	EU	Approved (Nov 2023)
TAK-577 <i>VONVENDI</i> (U.S., Japan) <i>VEYVONDI</i> (EU)	von Willebrand factor [recombinant] (injection)	Biologic and other	Adult prophylactic treatment of von Willebrand disease	EU	Approved (Nov 2023)
			Adult on-demand and surgery treatment of von Willebrand disease	China	Filed (Jan 2023)
			Pediatric on-demand and surgery treatment of von Willebrand disease	Global	P-III
TAK-672 <sup>2</sup> <i>OBIZUR</i> (U.S., EU)	Porcine Coagulation Factor VIII [recombinant] (injection)	Biologic and other	Acquired hemophilia A (AHA)	China Japan	Approved (Feb 2024) Approved (Mar 2024)
TAK-660 <i>ADYNOVATE</i> (U.S., Japan) <i>ADYNOVI</i> (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Biologic and other	Pediatric Hemophilia A	EU	P-III
			Hemophilia A	China	P-III

1. Partnership with GSK

2. Partnership with Ipsen

Additions since FY2023 Q3: None

Removals since FY2023 Q3: None



## Plasma-Derived Therapies Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-771 <sup>1</sup> <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase> <i>HYQVIA</i> (U.S., EU)	Immunoglobulin (IgG) + recombinant hyaluronidase replacement therapy (subcutaneous infusion)	Biologic and other	Pediatric indication for Primary Immunodeficiency	U.S.	Approved (Apr 2023)
			Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. EU	Approved (Jan 2024) Approved (Jan 2024)
			Primary Immunodeficiencies and Secondary Immunodeficiencies	Japan	Filed (Feb 2024)
			Chronic inflammatory demyelinating polyradiculoneuropathy and Multifocal Motor Neuropathy	Japan	P-III
TAK-664 <IG Infusion 20% (Human)> <i>CUVITRU</i> (U.S., EU, Japan)	Immunoglobulin 20% [human] (subcutaneous infusion)	Biologic and other	Primary Immunodeficiencies and Secondary Immunodeficiencies	Japan	Approved (Sep 2023)
			Secondary Immunodeficiencies	EU	Approved (Jan 2024)
<Anti-Inhibitor Coagulant Complex> <i>FEIBA</i> (U.S., EU, Japan)	Activated prothrombin complex concentrate [human](injection)	Biologic and other	FEIBA STAR label extension: Label updated to enable up to 5x faster infusion and a new presentation which allows for a 50% reduced volume of diluent for use in patients with hemophilia A or B with inhibitors	U.S. EU	Approved (June 2023) Approved (Dec 2023)
TAK-339 <IG Infusion 10% (Human)> <i>GAMMAGARD LIQUID</i> (U.S.) <i>KIOVIG</i> (EU)	Immunoglobulin 10% [human] (intravenous and subcutaneous infusion)	Biologic and other	Chronic inflammatory demyelinating polyradiculoneuropathy	U.S.	Approved (Jan 2024)
TAK-662 <i>CEPROTIN</i> (U.S., EU)	Protein C concentrate [human] (injection)	Biologic and other	Severe congenital protein C deficiency	Japan	Approved (Mar 2024)
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) Complete Response Letter (CRL) received (May 2023)
TAK-330 <i>PROTHROMPLEX TOTAL</i> (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> <i>GLOVENIN-I</i> (Japan)	Immunoglobulin (5%) [human] (injection)	Biologic and other	Autoimmune Encephalitis (AE)	Japan	P-III
TAK-881 <Facilitated 20% SCIG>	Immunoglobulin (20%) [human] + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Primary Immunodeficiencies	U.S. EU	P-III

### 1. Partnership with Halozyme

Additions since FY2023 Q3: None

Removals since FY2023 Q3: None

## Vaccines Pipeline

Development code Brand name (country/region)	Type of vaccine (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-003 <sup>1</sup> <i>QDENG</i> (EU) <sup>2</sup>	Tetravalent dengue vaccine (injection)	Biologic and other	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older	U.S.	Filing withdrawn (Jul 2023)
			For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older (booster extension)	-	P-III

1. In October 2022, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) recommended the approval of TAK-003 in Europe and in dengue-endemic countries participating in the parallel EU-M4all procedure. QDENG (TAK-003) was approved for use in the EU in December 2022.

2. QDENG (TAK-003) is also approved in Indonesia, Brazil, the U.K., Argentina, Colombia, Malaysia and Thailand.

Additions since FY2023 Q3: None

Removals since FY2023 Q3: None