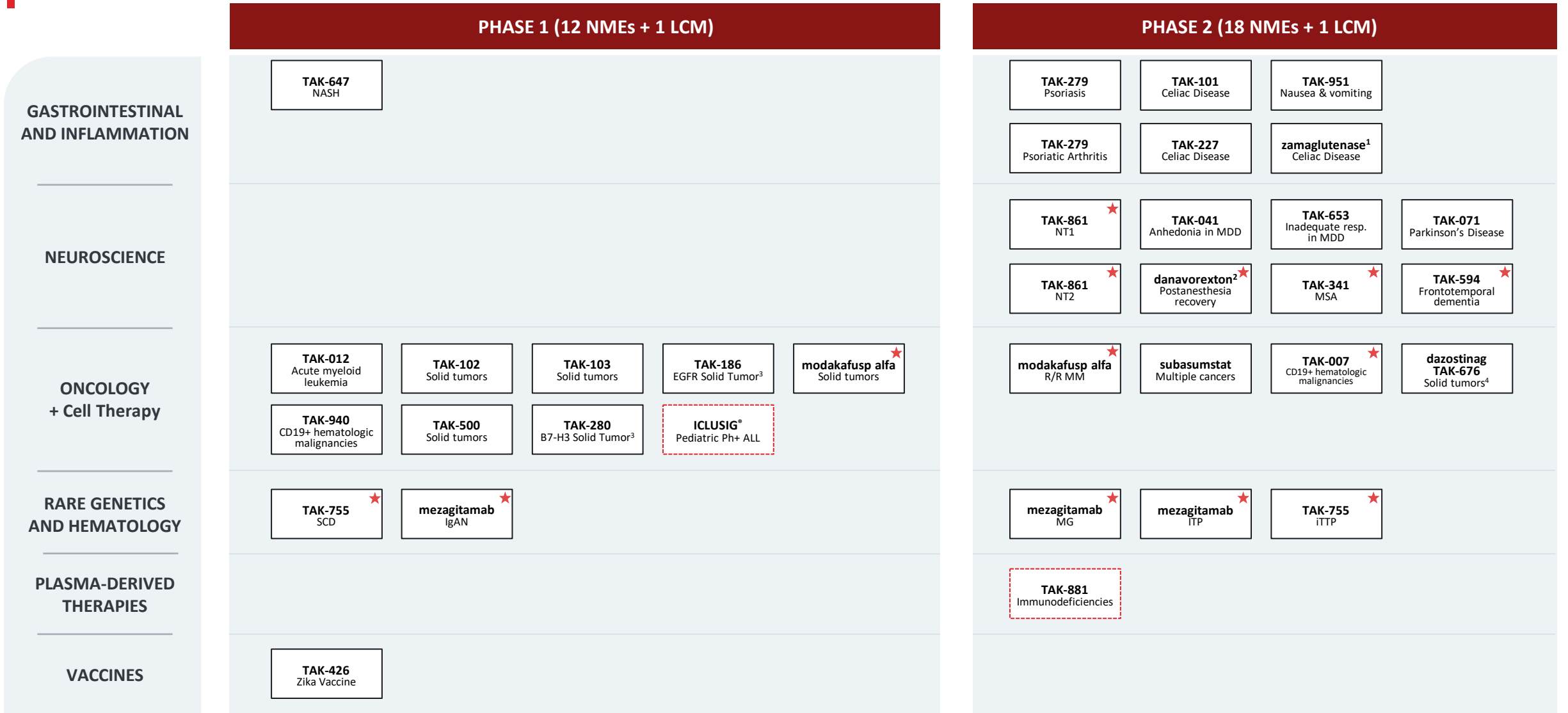


# Consolidated Development Pipeline by Phase



1. Zamaglutense is the INN for TAK-062  
 2. Danavorexton is the INN for TAK-925  
 3. Currently in phase 1 of a phase 1/2 trial  
 4. Currently in phase 2 of a phase 1/2 trial

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

NME

LCM

# Consolidated Development Pipeline by Phase



- GASTROINTESTINAL AND INFLAMMATION
- NEUROSCIENCE
- ONCOLOGY + Cell Therapy
- RARE GENETICS AND HEMATOLOGY
- PLASMA-DERIVED THERAPIES
- VACCINES

PHASE 3 (5 NMEs + 21 LCMs)			
fazirsiran AATD Liver Disease ★	ENTYVIO® Pediatric UC	ALOFISEL® Perianal Fistulas in CD (US) <sup>1</sup> ★	maralixibat ALGS (JP) ★
ENTYVIO® GvHD Prophylaxis ★	ENTYVIO® Pediatric CD	ALOFISEL® Pediatric perianal Fistulas in CD ★	maralixibat PFIC (JP) ★
soticlestat DS ★	soticlestat LGS ★	pabinafusp alfa Hunter Syndrome ★	
CABOMETYX® mCRC combo w/atezolizumab (JP)	ICLUSIG® 1L Ph+ ALL (US)		
NINLARO® Maint. ND MM post-SCT (US, EU) ★	relugolix Prostate cancer (JP, CN)		
TAK-755 cTTP (CN) ★	LIVTENCITY® Post-transplant CMV infection (JP) ★	ADYNOVATE® recombinant Factor VIII HemA (CN)	
VONVENDI® vWD Adult Prophylaxis (CN) ★	VONVENDI® vWD Pediatric On-demand & Surgery ★	ADYNOVATE® recombinant Factor VIII Pediatric HemA (EU)	
HYQVIA® CIDP, MMN (JP) ★	HYQVIA® PID (JP)	Prothromplex DOAC Reversal (US)	
TAK-880 IgG – Low IgA (US, EU)	Glovenin-I Autoimmune Encephalitis (JP) ★		
QDENGA® Dengue Vaccine Booster			

FILED (3 NME + 18 LCMs)			
ENTYVIO® SC UC (US)	VOCINTI® H. Pylori (CN)	TAK-721 Eosinophilic esophagitis (US) ★	
ENTYVIO® SC CD (JP)	ENTYVIO® SC CD (US)		
fruquintinib mCRC (US)	fruquintinib mCRC (JP)	ADCETRIS® FL HL Stage III (EU)	
fruquintinib mCRC (EU)	ADCETRIS® FL PTCL-NOS (EU) ★	ADCETRIS® R/R CTCL (JP) ★	
TAK-755 cTTP (US) ★	TAK-755 cTTP (JP) ★	OBIZUR® Recomb antihemophilic factor porcine (JP) ★	VONVENDI® vWD On-demand & Surgery (CN) ★
TAK-755 cTTP (EU) ★	TAKHZYRO® Pediatric HAE (EU) ★	OBIZUR® Recomb antihemophilic factor porcine (CN) ★	VONVENDI® vWD Adult Prophylaxis (EU) ★
HYQVIA® CIDP (US) ★	HYQVIA® Pediatric PID (US) ★	CUVITRU® PID, SID (JP)	
HYQVIA® CIDP (EU) ★	GAMMAGARD LIQUID® CIDP (US)	CEPROTIN® SCPCD (JP)	

1. ALOFISEL Study did not meet primary endpoint; further analysis ongoing.

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

APPROVED 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>CD</b>	Crohn's disease
<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>IND</b>	investigational new drug
<b>INN</b>	international non-proprietary name
<b>IRR</b>	incidence rate ratio
<b>IT</b>	intrathecal
<b>ITP</b>	Immune thrombocytopenic purpura
<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

- The following table lists the pipeline assets that we are clinically developing as of October 26, 2023 (the date of our earnings release for the second quarter ended September 30, 2023), unless otherwise specifically noted. 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) Filed (Sep 2023)
			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	Filed (Aug 2022)
TAK-721 <budesonide>	Glucocorticosteroid (oral)	Small molecule	Eosinophilic esophagitis	U.S.	Filed (Sep 2023)
Cx601 <darvadstrocel> ALOFISEL (EU, Japan)	A suspension of allogeneic expanded adipose-derived stem cells (injection)	Biologic and other	Refractory complex perianal fistulas in patients with Crohn's disease	U.S.	P-III <sup>1</sup>
			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-227/ZED1227 <sup>4</sup>	Transglutaminase 2 inhibitor (oral)	Small molecule	Celiac disease	-	P-II (b)
TAK-279	TYK2 inhibitor (oral)	Small molecule	Psoriasis	-	P-II (b)
			Psoriatic Arthritis	-	P-II (b)
TAK-062 <zamaglutinase>	Glutenase (oral)	Biologic and other	Celiac disease	-	P-II
TAK-101 <sup>5</sup>	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II
TAK-951	Peptide agonist (subcutaneous infusion)	Peptide/Oligo-nucleotide	Nausea and vomiting	-	P-II
TAK-647 <sup>6</sup>	Anti MAdCAM-1 antibody (injection)	Biologic and other	Nonalcoholic Steatohepatitis (NASH)	-	P-I

1. ALOFISEL Phase 3 ADMIRE CD-II study to support U.S. filing did not meet primary endpoint.
2. Partnership with Arrowhead Pharmaceuticals, Inc.
3. Partnership with Mirum Pharmaceuticals.
4. Partnership with Zedira and Dr. Falk Pharma.
5. Partnership with COUR Pharmaceuticals.
6. Partnership with Pfizer.

Additions since FY2023 Q1: TAK-721 for Eosinophilic esophagitis (Filed, U.S.)

Removals since FY2023 Q1: None

## Neuroscience Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-935 <soficicostat>	CH24H inhibitor (oral)	Small molecule	Dravet syndrome	Global	P-III
			Lennox-Gastaut syndrome	Global	P-III
TAK-141/JR-141 <sup>1</sup> <pabinafusp alfa>	Fusion protein of an antibody against the human transferrin receptor and iduronate-2-sulfatase [recombinant] (injection)	Biologic	Hunter syndrome (CNS and somatic symptoms)	EU	P-III
TAK-861	Orexin 2R agonist (oral)	Small molecule	Narcolepsy type 1	-	P-II (b)
			Narcolepsy type 2	-	P-II (b)
TAK-071	M1 positive allosteric modulator (M1PAM) (oral)	Small molecule	Parkinson's disease	-	P-II
TAK-041/NBI-846 <sup>2</sup>	GPR139 agonist (oral)	Small molecule	Anhedonia in major depressive disorder (MDD)	-	P-II
TAK-653/NBI-845 <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/DNL593 <sup>4</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

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

Additions since FY2023 Q1: None

Removals since FY2023 Q1: TAK-920/DNL919 for Alzheimer's disease (P-I, discontinued), TAK-611 for Metachromatic leukodystrophy (P-II, 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	Filed (Feb 2023)
			Front line Peripheral T-cell lymphoma-Not Otherwise Specified (PTCL-NOS)	EU	Filed (Jul 2023)
TAK-113 <sup>2</sup> <fruquintinib>	VEGFR inhibitor (oral)	Small molecule	Previously treated metastatic Colorectal Cancer (mCRC)	U.S. EU Japan	Filed (Mar 2023) Filed (Jun 2023) Filed (Sep 2023)
MLN9708 <ixazomib> <i>NINLARO</i> (Global)	Proteasome inhibitor (oral)	Small molecule	Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant (TOURMALINE-MM3)	U.S. EU	P-III P-III
<cabozantinib> <sup>3</sup> <i>CABOMETYX</i> (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab <sup>4</sup>	Japan	P-III
<ponatinib> <i>ICLUSIG</i> (U.S.)	BCR-ABL inhibitor (oral)	Small molecule	Front line Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	U.S.	P-III
			Pediatric indication for Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	-	P-I
TAK-385 <relugolix>	LH-RH antagonist (oral)	Small molecule	Prostate cancer	Japan China	P-III P-III
TAK-981 <subasumstat>	SUMO inhibitor (injection)	Small molecule	Multiple cancers	-	P-II
TAK-573 <sup>5</sup> <modakafusp alfa>	Anti-CD38-targeted IgG4 genetically fused with an attenuated IFN $\alpha$ (injection)	Biologic and other	Relapsed/refractory Multiple Myeloma	-	P-II
			Solid tumors	-	P-I
TAK-007 <sup>6</sup>	CD19 CAR-NK (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-II
TAK-676 <dazostinag>	STING agonist (injection)	Small molecule	Solid tumors	-	P-II
TAK-102 <sup>7</sup>	GPC3 CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-103 <sup>7</sup>	Mesothelin CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-500	STING agonist antibody drug conjugate (injection)	Biologic and other	Solid tumors	-	P-I
TAK-940 <sup>8</sup>	CD19 1XX CAR-T (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	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 (V $\delta$ 1) gamma delta ( $\gamma\delta$ ) T cells (injection)	Cell and gene therapy	Relapsed/refractory Acute Myeloid Leukemia	-	P-I

1. Partnership with Seagen, Inc.
2. Partnership with HUTCHMED
3. Partnership with Exelixis, Inc.
4. Partnership with Chugai Pharmaceutical. Takeda operates P-III development
5. Partnership with Teva Pharmaceutical Industries Ltd.
6. Partnership with The University of Texas MD Anderson Cancer Center
7. Partnership with Noile-Immune Biotech, Inc.
8. Partnership with Memorial Sloan Kettering Cancer Center

\* Event occurred after the end of the Q2 reporting period: Update after October 1, 2023

Additions since FY2023 Q1: None

Removals since FY2023 Q1:

TAK-788 for Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion (Japan, P-III) (Global voluntary withdrawal)

TAK-788 for Treatment Naïve Non-Small Cell Lung Cancer with EGFR exon 20 insertion (Global, P-III) (Global voluntary withdrawal)



## Rare Genetics and Hematology 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	Filed (Dec 2022)
			Treatment of CMV Infection/disease Post Transplantation (Including HSCT)	Japan	P-III
TAK-743 <lanadelumab> <i>TAKHZYRO</i> (Global)	Plasma kallikrein inhibitor (injection)	Biologic and other	Pediatric Hereditary Angioedema	EU	Filed (Dec 2022)
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	Filed (Jun 2022) Filed (Jun 2023)
TAK-577 <i>VONVENDI</i> (U.S., Japan) <i>VEYVONDI</i> (EU)	von Willebrand factor [recombinant] (injection)	Biologic and other	Adult on-demand and surgery treatment of von Willebrand disease	China	Filed (Jan 2023)
			Adult prophylactic treatment of von Willebrand disease	EU China	Filed (Mar 2023) P-III
			Pediatric on-demand and surgery treatment of von Willebrand disease	Global	P-III
TAK-755 <sup>3</sup> <apadamtase alfa/ cinaxadamtase alfa>	Replacement of the deficient ADAMTS13 enzyme (injection)	Biologic and other	Congenital Thrombotic Thrombocytopenic Purpura	U.S. EU Japan China	Filed (May 2023) Filed (May 2023) Filed (Aug 2023) P-III
			Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II (b) P-II (b)
			Sickle cell disease	U.S.	P-I
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
TAK-079 <sup>4</sup> <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Myasthenia gravis	-	P-II
			Immune thrombocytopenic purpura	-	P-II
			Systemic lupus erythematosus	-	P-I/II
			Immunoglobulin A nephropathy	-	P-I

- Partnership with GSK
- Partnership with Ipsen
- Partnership with KM Biologics.
- A clinical trial for Relapsed/refractory Multiple Myeloma was completed.

Additions since FY2023 Q1: None

Removals since FY2023 Q1: 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	Filed (Feb 2023) Filed (Mar 2023)
			Chronic inflammatory demyelinating polyradiculoneuropathy and Multifocal Motor Neuropathy	Japan	P-III
			Primary Immunodeficiencies	Japan	P-III
TAK-664 <IG Infusion 20% (Human)> <i>CUVITRU</i> (U.S., EU)	Immunoglobulin 20% [human] (subcutaneous infusion)	Biologic and other	Primary Immunodeficiencies and Secondary Immunodeficiencies	Japan	Approved (Sep 2023)
TAK-662 <i>CEPROTIN</i> (U.S., EU)	Protein C concentrate [human] (injection)	Biologic and other	Severe congenital protein C deficiency	Japan	Filed (Apr 2023)
TAK-339 <IG Infusion 10% (Human)> <i>GAMMAGUARD LIQUID</i> (U.S.) <i>KIOVIG</i> (EU)	Immunoglobulin 10% [human] (intravenous and subcutaneous infusion)	Biologic and other	Chronic inflammatory demyelinating polyradiculoneuropathy	U.S.	Filed (May 2023)
TAK-880 <10% IVIG (Low IgA)>	Immunoglobulin (10%) [human] (injection) (Low IgA)	Biologic and other	Primary Immunodeficiencies and Multifocal Motor Neuropathy	U.S. EU	Complete Response Letter (CRL) received (May 2023) Filing in preparation <sup>2</sup>
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	Immunodeficiencies	U.S. E.U.	P-I/II

1. Partnership with Halozyme

2. Non-interventional study to collect data is in progress

Additions since FY2023 Q1: None

Removals since FY2023 Q1: 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
TAK-426 <sup>3</sup>	Zika vaccine (injection)	Biologic and other	Active immunization for the prevention of disease caused by Zika virus	-	P-I

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 and Thailand.

3. Partnership with The Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Government

Additions since FY2023 Q1: None

Removals since FY2023 Q1: TAK-019/NVX CoV2373 for Active immunization for the prevention of COVID-19 (heterologous booster) (Japan, P-III, trial completed)