

# Consolidated Development Pipeline by Phase



	PHASE 1 (14 NMEs + 1 LCM)					PHASE 2 (18 NMEs + 1 LCM)					
<b>GASTROINTESTINAL AND INFLAMMATION</b>	TAK-647 NASH <sup>1</sup>					TAK-279 Psoriasis		TAK-101 Celiac Disease	TAK-951 Nausea & vomiting		
						TAK-279 Psoriatic Arthritis		TAK-227 Celiac Disease	zamaglutinase <sup>2</sup> Celiac Disease		
<b>NEUROSCIENCE</b>	TAK-920 Alzheimer's Disease					TAK-861 NT1	TAK-611 MLD (intrathecal)	TAK-041 Anhedonia in MDD	TAK-653 Inadequate resp. in MDD	TAK-071 Parkinson's Disease	
						TAK-861 NT2	danavorexton <sup>3</sup> Postanesthesia recovery	TAK-341 MSA	TAK-594 Frontotemporal dementia		
<b>ONCOLOGY + Cell Therapy</b>	TAK-012 Acute myeloid leukemia <sup>1</sup>	TAK-102 Solid tumors	TAK-103 Solid tumors	TAK-186 EGFR Solid Tumor <sup>4</sup>	modakafusp alfa Solid tumors	modakafusp alfa R/R MM	subasumstat Multiple cancers	TAK-007 CD19+ hematologic malignancies			
	TAK-940 CD19+ hematologic malignancies	TAK-500 Solid tumors	TAK-676 Solid tumors	TAK-280 B7-H3 Solid Tumor <sup>4</sup>	ICLUSIG® Pediatric Ph+ ALL						
<b>RARE GENETICS AND HEMATOLOGY</b>	TAK-755 SCD	mezagitamab IgAN				mezagitamab MG	mezagitamab ITP	TAK-755 iTTP			
<b>PLASMA-DERIVED THERAPIES</b>						TAK-881 Immunodeficiencies					
<b>VACCINES</b>	TAK-426 Zika Vaccine										

1. Study actively recruiting  
 2. Zamaglutinase is the INN for TAK-062  
 3. Danavorexton is the INN for TAK-925  
 4. Currently in phase 1 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



## PHASE 3 (7 NMEs + 23 LCMs)

## FILED (2 NME + 16 LCMs)

### GASTROINTESTINAL AND INFLAMMATION

<b>fazirsiran</b> ★ AATD Liver Disease	<b>ENTYVIO</b> ® Pediatric UC	<b>ENTYVIO</b> ® ★ GvHD Prophylaxis	<b>ALOFISEL</b> ® ★ Perianal Fistulas in CD (US)	<b>maralixibat</b> ★ ALGS (JP)
<b>ENTYVIO</b> ® SC CD (US)	<b>ENTYVIO</b> ® Pediatric CD	<b>ALOFISEL</b> ® ★ Pediatric perianal Fistulas in CD	<b>maralixibat</b> ★ PFIC (JP)	

<b>ENTYVIO</b> ® SC UC (US)	<b>VOCINTI</b> ® <i>H. Pylori</i> (CN)
<b>ENTYVIO</b> ® SC CD (JP)	

### NEUROSCIENCE

<b>soticlestat</b> ★ DS	<b>soticlestat</b> ★ LGS	<b>pabinafusp alfa</b> ★ Hunter Syndrome
----------------------------	-----------------------------	---

### ONCOLOGY + Cell Therapy

<b>EXKIVITY</b> ® ★ 1L NSCLC EGFR exon 20	<b>fruquintinib</b> mCRC (JP)	<b>ICLUSIG</b> ® 1L Ph+ ALL (US)
<b>NINLARO</b> ® ★ Maint. ND MM post-SCT (US, EU)	<b>relugolix</b> Prostate cancer (JP, CN)	<b>CABOMETYX</b> ® mCRPC combo w/atezolizumab (JP)

<b>fruquintinib</b> mCRC (US)	<b>ADCETRIS</b> ® FL HL Stage III (EU)	<b>ADCETRIS</b> ® ★ R/R CTCL (JP)
<b>fruquintinib</b> mCRC (EU)	<b>ADCETRIS</b> ® ★ FL PTCL-NOS (EU)	

### RARE GENETICS AND HEMATOLOGY

<b>TAK-755</b> ★ cTTP (JP, CN)	<b>LIVTENCITY</b> ® ★ Post-transplant CMV infection (JP)	<b>ADYNOVATE</b> ® recombinant Factor VIII HemA (CN)
<b>VONVENDI</b> ® ★ vWD Adult Prophylaxis (CN)	<b>VONVENDI</b> ® ★ vWD Pediatric On-demand & Surgery	<b>ADYNOVATE</b> ® recombinant Factor VIII Pediatric HemA (EU)

<b>TAK-755</b> ★ cTTP (US)	<b>OBIZUR</b> ® ★ Recomb antihemophilic factor porcine (JP)	<b>VONVENDI</b> ® ★ vWD On-demand & Surgery (CN)	<b>TAKHZYRO</b> ® ★ Pediatric HAE (EU)
<b>TAK-755</b> ★ cTTP (EU)	<b>OBIZUR</b> ® ★ Recomb antihemophilic factor porcine (CN)	<b>VONVENDI</b> ® ★ vWD Adult Prophylaxis (EU)	

### PLASMA-DERIVED THERAPIES

<b>HYQVIA</b> ® ★ CIDP, MMN (JP)	<b>HYQVIA</b> ® PID (JP)	<b>Prothromplex</b> DOAC Reversal (US)
<b>TAK-880</b> IgG – Low IgA (EU) <sup>1</sup>	<b>Glovenin-I</b> ★ Autoimmune Encephalitis (JP)	

<b>HYQVIA</b> ® ★ CIDP (US)	<b>CUVITRU</b> ® PID, SID (JP)	<b>GAMMAGARD LIQUID</b> ® CIDP (US)
<b>HYQVIA</b> ® ★ CIDP (EU)	<b>CEPROTIN</b> ® SCPCD (JP)	

### VACCINES

<b>Nuvaxovid</b> ® COVID-19 Vaccine Booster (JP)	<b>QDENGAR</b> ® Dengue Vaccine Booster
---	--

1. In the U.S., TAK-880 received a CRL from the FDA, re-submission timing under evaluation.

★ 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>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>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>EASL</b>	European Association for the Study of the Liver
<b>EGFR</b>	epidermal growth factor receptor

<b>EMA</b>	European Medicines Agency
<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>ISTH</b>	International Society on Thrombosis and Haemostasis
<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>JPNS</b>	Journal of the Peripheral Nervous System
<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 July 27, 2023 (the date of our annual earnings release), 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> <i>ENTYVIO</i> (Global)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Biologic and other	Ulcerative colitis (subcutaneous formulation)	U.S.	Filed (Apr 2023)
			Crohn's disease (subcutaneous formulation)	Japan U.S.	Filed (Oct 2022) P-III
			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> <i>TAKECAB</i> (Japan) <i>VOCINTI</i> (China)	Potassium-competitive acid blocker (oral)	Small molecule	Acid related diseases (adjunct to <i>Helicobacter pylori</i> eradication)	China	Filed (Aug 2022)
Cx601 <darvadstrocel> <i>ALOFISEL</i> (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
			Pediatric indication for refractory complex perianal fistulas in patients with Crohn's disease	EU Japan	P-III P-III
TAK-999 <sup>1</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>2</sup> <maralixibat>	IBAT inhibitor (oral)	Small molecule	Alagille Syndrome	Japan	P-III
			Progressive Familial Intrahepatic Cholestasis	Japan	P-III
TAK-227/ZED1227 <sup>3</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>4</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>5</sup>	Anti MAdCAM-1 antibody (injection)	Biologic and other	Nonalcoholic Steatohepatitis (NASH)	-	P-I <sup>6</sup>

1. Partnership with Arrowhead Pharmaceuticals, Inc.
2. Partnership with Mirum Pharmaceuticals.
3. Partnership with Zedira and Dr. Falk Pharma.
4. Acquired development and commercialization license for TAK-101 from COUR Pharmaceuticals.
5. Partnership with Pfizer.
6. Study actively recruiting

Additions since FY2022 Q4: None

Removals since FY2022 Q4: TAK-105 for Nausea and vomiting (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 <sothicestat>	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 systems atrophy (MSA)	-	P-II
TAK-611	Human arylsulfatase A for intrathecal administration [recombinant] (injection)	Biologic and other	Metachromatic leukodystrophy	-	P-II <sup>4</sup>
TAK-594/DNL593 <sup>5</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-920/DNL919 <sup>5</sup>	Brain-penetrant TREM2 agonist monoclonal antibody (injection)	Biologic and other	Alzheimer's disease	-	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. Phase 2 trial topline results did not meet primary and secondary endpoints.
5. Partnership with Denali Therapeutics. Denali leads P-I development.

Additions since FY2022 Q4: None  
Removals since FY2022 Q4: None

## Oncology Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-113 <sup>1</sup> <fruquintinib>	VEGFR inhibitor (oral)	Small molecule	Previously treated metastatic Colorectal Cancer (mCRC)	U.S. EU Japan	Filed (Mar 2023) Filed (Jun 2023) P-III
SGN-35 <sup>2</sup> <brentuximab vedotin> ADCETRIS (EU, Japan, China)	CD30 monoclonal antibody-drug conjugate (injection)	Biologic and other	Relapsed or refractory cutaneous T-cell lymphoma	Japan	Filed (Feb 2023)
			Front line Hodgkin's lymphoma – Stage III	EU	Filed (Mar 2023)
			Front line Peripheral T-cell lymphoma-Not Otherwise Specified (PTCL-NOS)	EU	Filed (Jul 2023)*
TAK-788 <mobocertinib> EXKIVITY (U.S., China)	EGFR/HER2 exon 20 inhibitor (oral)	Small molecule	Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion	EU <sup>3</sup> Japan	Filing withdrawn (Jul 2022) P-III
			Treatment Naïve Non-Small Cell Lung Cancer with EGFR exon 20 insertion	Global	P-III <sup>4</sup>
MLN9708 <ixazomib> NINLARO (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>5</sup> CABOMETYX (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab <sup>6</sup>	Japan	P-III
<ponatinib> ICLUSIG (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>7</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>8</sup>	CD19 CAR-NK (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-II
TAK-102 <sup>9</sup>	GPC3 CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-103 <sup>9</sup>	Mesothelin CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I

TAK-676	STING agonist (injection)	Small molecule	Solid tumors	-	P-I
TAK-500	STING agonist antibody drug conjugate (injection)	Biologic and other	Solid tumors	-	P-I
TAK-940 <sup>10</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 <sup>11</sup>

1. Partnership with HUTCHMED
2. Partnership with Seagen, Inc.
3. Following discussions with the EMA, Takeda decided to withdraw the marketing authorization application (MAA).
4. Phase 3 EXCLAIM-2 trial stopped for futility; discussions with global regulatory authorities ongoing
5. Partnership with Exelixis, Inc.
6. Partnership with Chugai Pharmaceutical. Takeda operates P-III development
7. Partnership with Teva Pharmaceutical Industries Ltd.
8. Partnership with The University of Texas MD Anderson Cancer Center
9. Partnership with Noile-Immune Biotech, Inc.
10. Partnership with Memorial Sloan Kettering Cancer Center
11. Study actively recruiting

\* Event occurred after the end of the Q1 reporting period: Update after July 1, 2023

Additions since FY2022 Q4:

SGN-35 for Front line Peripheral T-cell lymphoma-Not Otherwise Specified (PTCL-NOS) (Filed, EU)

TAK-012 for Relapsed/refractory Acute Myeloid Leukemia (P-I)

Removals since FY2022 Q4: None



## 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) P-III P-III
			Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II P-II
			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.
- Relapsed/refractory Multiple Myeloma will continue until trial completion.

Additions since FY2022 Q4: TAK-660 for Hemophilia A (China, P-III)

Removals since FY2022 Q4: 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-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-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	Filed (Oct 2022)
TAK-339 <IG Infusion 10% (Human)> <i>GAMMAGUARD</i> <i>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) <sup>2</sup> Filing in preparation <sup>3</sup>
TAK-330 <i>PROTHROMPLEX</i> <i>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. TAK-880 received a CRL from the FDA; re-submission timing is under evaluation.

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

Additions since FY2022 Q4: TAK-339 for Chronic inflammatory demyelinating polyradiculoneuropathy (Filed, U.S.)

Removals since FY2022 Q4: 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> A (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-019/ NVX-CoV2373 <sup>3</sup> <i>NUVAXOVID</i> Intramuscular Injection (Japan)	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19 (heterologous booster)	Japan	P-III
TAK-426 <sup>4</sup>	Zika vaccine (injection)	Biologic and other	Active immunization for the prevention of disease caused by Zika virus	-	P-I

1. Takeda participated in the European Medicines Agency's (EMA) parallel assessment of a medicinal product for use in EU, and through the EU-M4all procedure for countries outside of the EU. In October 2022, the Committee for Medicinal Products for Human Use (CHMP) of the EMA recommended the approval of TAK-003 in Europe and in dengue-endemic countries participating in the parallel EU-M4all procedure.

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

3. Partnership with Novavax, Inc.

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

\* Event occurred after the end of the Q1 reporting period: Update after July 1, 2023

Additions since FY2022 Q4: None

Removals since FY2022 Q4: None