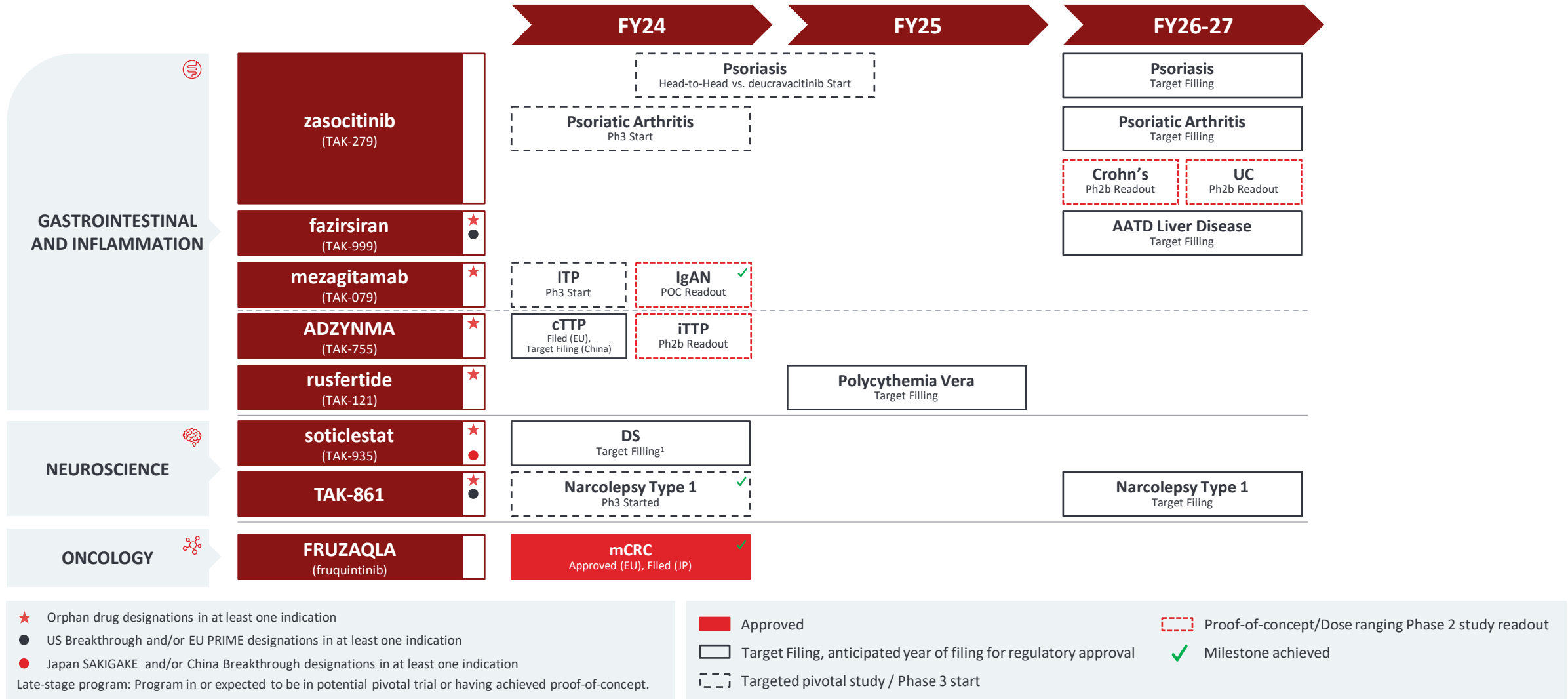


# Developing Life Transforming Medicines for Rare and More Prevalent Diseases: Late-Stage Programs have the Potential to Generate Significant Value

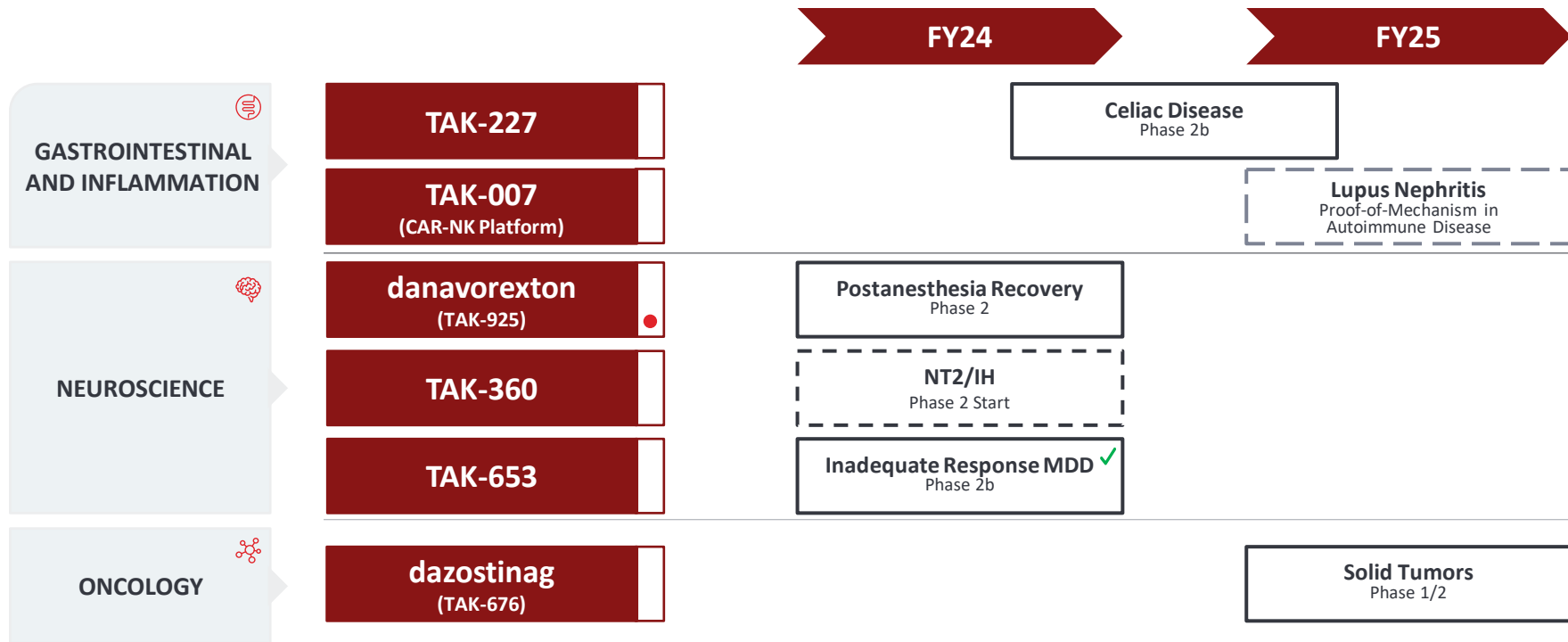


★ Orphan drug designations in at least one indication  
 ● US Breakthrough and/or EU PRIME designations in at least one indication  
 ● Japan SAKIGAKE and/or China Breakthrough designations in at least one indication  
 Late-stage program: Program in or expected to be in potential pivotal trial or having achieved proof-of-concept.

■ Approved  
 □ Target Filing, anticipated year of filing for regulatory approval  
 □ Targeted pivotal study / Phase 3 start  
 □ Proof-of-concept/Dose ranging Phase 2 study readout  
 ✓ Milestone achieved

1. Soticlestat DS totality of Phase 3 data suggests potential clinically meaningful benefit despite missing primary endpoint. Next step discuss potential filing with FDA. All timelines are approximate estimates as of July 31<sup>st</sup>, 2024, are subject to change and are subject to clinical and regulatory success. Table only shows selected R&D milestones and is not comprehensive. For full glossary of abbreviations please refer to appendix.

# Impactful Pipeline Milestones for Early to Mid-Stage Programs Advance Science and Address Unmet Patient Needs



Proof-of-concept (POC): Achieving proof-of-concept means obtaining clinical data sufficient to initiate pivotal trials or late-stage development. A “readout(s)” for a clinical trial occurs when Takeda has (1) received the relevant clinical data, (2) completed any necessary analysis and review of such clinical data, and (3) in instances where it is required or otherwise common convention or practice, consulted with applicable regulatory authorities regarding such clinical data. Where a readout is indicated for a class of related indications (e.g., solid tumors) involving multiple POC clinical trials, such readout occurs upon the earlier of (1) the first achievement of POC in an indication in such class, or (2) the conclusion of all of the POC clinical trials in such class.

- Proof-of-concept to inform Go/No-go to pivotal trial
- Phase 2 Start
- Clinical proof-of-mechanism
- Japan SAKIGAKE and/or China Breakthrough designations in at least one indication
- Milestone achieved

All timelines are approximate estimates as of July 31<sup>st</sup>, 2024, are subject to change and are subject to clinical and regulatory success. Table only shows selected R&D milestones and is not comprehensive. For full glossary of abbreviations please refer to appendix.

# Important Near-Term LCM Expansions Represent Significant Growth Opportunities



	FY24	FY25
<b>GASTROINTESTINAL AND INFLAMMATION</b>	<b>maralixibat</b> ✓ Filed ALGS, PFIC (Japan)	<b>ENTYVIO</b> Target Filing Crohn's/UC Peds (US, EU)
<b>ONCOLOGY</b>	<b>ADCETRIS</b> ✓ Filed FL HL BrECADD (EU) <sup>1</sup>	
	<b>CABOMETYX</b> Target Filing CRPC (Japan)	
<b>PLASMA-DERIVED THERAPIES</b>	<b>HYQVIA</b> Target Filing CIDP, MMN (Japan)	
	<b>Glovenin-I 10%</b> Target filing Multiple Indications (Japan)	
	<b>TAK-880</b> Target Filing RTU IgG low IgA (US)	
<b>VACCINES</b>	<b>QDenga</b> Rolling/ongoing filings in endemic and travel markets <sup>2</sup>	

■ Approved    
  Target Filing    
 ✓ Milestone achieved

1. Submission based on data from German Hodgkin Study Group HD21 trial  
 2. QDenga approved in Vietnam (May 2024), Israel (May 2024)

All timelines are approximate estimates as July 31<sup>st</sup>, 2024, are subject to change and are subject to clinical and regulatory success. Table only shows selected R&D milestones and 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

<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>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>CP-CML</b>	chronic-phase chronic myeloid leukemia
<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>cTTP</b>	congenital thrombotic thrombocytopenic purpura
<b>DOAC</b>	direct oral anti-coagulation
<b>DS</b>	Dravet syndrome

<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>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>ISTH</b>	International Society on Thrombosis and Haemostasis
<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>LS</b>	least square
<b>LTE</b>	long-term extension
<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>MM</b>	multiple myeloma
<b>MMN</b>	multifocal motor neuropathy
<b>MSA</b>	multiple system atrophy
<b>MWT</b>	maintenance of wakefulness test
<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>PNS</b>	Peripheral Nerve Society
<b>POC</b>	proof of concept
<b>PR</b>	platelet response
<b>PRIME</b>	Priority medicines scheme by EMA
<b>PROC</b>	platinum-resistant ovarian cancer
<b>QD</b>	quaque die, every day
<b>QOL</b>	quality of life
<b>R/R</b>	relapsed/refractory
<b>RTU</b>	ready to use
<b>SC</b>	subcutaneous formulation
<b>SCD</b>	sickle cell disease
<b>SCT</b>	stem cell transplant
<b>SEM</b>	standard error of the mean
<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