

10 LATE-STAGE DEVELOPMENT PROGRAMS WITH UPCOMING NME FILING AND EXPANSION OPPORTUNITIES



		FY21	FY22	FY23	FY24	FY25-27
ONCOLOGY	EXKIVITY	2L NSCLC ¹ Approved US, UK	2L NSCLC ¹ Filed EU, China		1L NSCLC ¹ Target Filing	
	modakafusp alfa	R/R MM Ph1 POC	R/R MM Ph2 Start ²			R/R MM Target Filing
RARE GENETICS & HEMATOLOGY	LIVTENCITY	R/R CMV Approved US	R/R CMV Filed EU	1L CMV Target Filing US, EU	R/R CMV Target Filing China	Post-transplant CMV Target Filing Japan
	TAK-755	iTTP Ph2 POC		cTTP Target Filing US	cTTP Target Filing EU, JP, China	iTTP Ph2b Read-Out
	TAK-611				MLD (IT) Ph2 Read-Out ³	
	pabinafusp alfa	Hunter Syndrome Ph3 Start				Hunter Syndrome Target Filing
NEUROSCIENCE	soticlestat	DS, LGS Ph3 Start			DS, LGS Target Filing	
GASTRO-ENTEROLOGY	fazirsiran (TAK-999)	AATD Liver Disease Ph2 POC	AATD Liver Disease Ph3 Start			AATD Liver Disease Target Filing
VACCINES	Nuvaxovid (TAK-019)		COVID-19 Vaccine Approved Japan			
	TAK-003	Dengue Vaccine Filed EU ⁴	Dengue Vaccine Target Filing US			

1. Non-small cell lung cancer with EGFR exon 20 insertion mutations
2. Pursuing single agent and multiple combination studies in R/R MM
3. Single arm Phase 2, timelines and filing plans will follow the data.
4. EU approval is expected to be referenced by many endemic countries for local approval. Filed in FY2020.

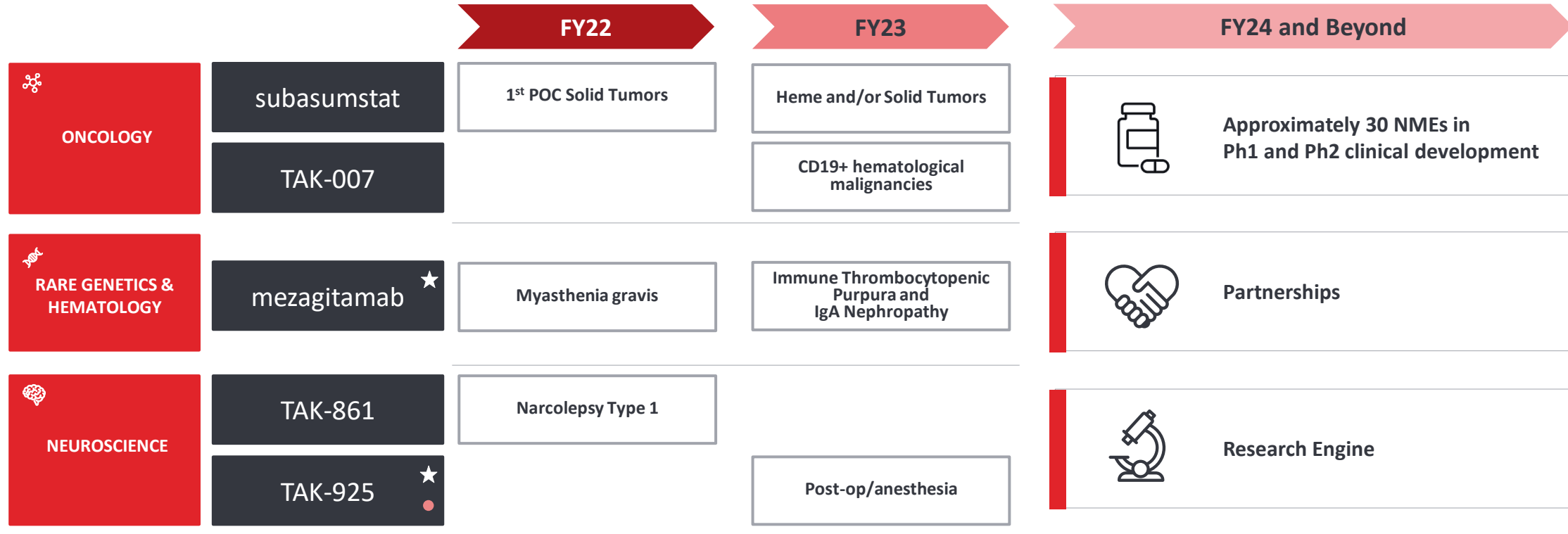
- US Breakthrough and/or EU PRIME designations in at least one indication
- Japan SAKIGAKE and/or China Breakthrough designations in at least one indication
- ☆ Orphan drug designations in at least one indication

- Approved
- Proof-of-concept/Ph2 study read-out
- Study start
- Target Filing, anticipated year of filing for regulatory approval
- Milestone achieved

Late-stage program: Program in or expected to be in potential pivotal trial or having achieved proof-of-concept.

All timelines are approximate estimates as of May 11, 2022 and are subject to change. Table only shows selected R&D milestones and is not comprehensive. For full glossary of abbreviations please refer to appendix.

KEY PROOF-OF-CONCEPT READOUTS IN FY22/23 EXPECTED TO ADD TO LATE-STAGE PIPELINE AND GLOBAL FILINGS IN MID/LATE 2020'S



● Japan SAKIGAKE and/or China Breakthrough designations in at least one indication
 ☆ Orphan drug designations in at least one indication
 □ Target proof-of-concept read-out

Proof-of-concept (POC): Achieving proof-of-concept means obtaining clinical data sufficient to initiate pivotal trials.

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LCM MILESTONES FOR OUR GROWTH & LAUNCH AND OTHER KEY PRODUCTS



	FY21	FY22	FY23
 ONCOLOGY	CABOMETYX ✓ Approved 1L RCC + nivo Japan	CABOMETYX Target Filing NSCLC, CRPC Japan	ICLUSIG Target Filing 1L Ph+ ALL US
	ALUNBRIG ✓ Approved ALK+ NSCLC China		
	ALUNBRIG Study read out H-2-H vs Alectinib in 2L ¹		
 RARE GENETICS & HEMATOLOGY	TAKHZYRO ✓ Approved HAE Japan	TAKHZYRO Target Filing Pediatric HAE US, EU	TAKHZYRO Target Filing BMA US
	VONVENDI ✓ Approved vWD Prophylaxis US, Japan		
 GASTRO-ENTEROLOGY	ENTYVIO ✓ Approved active chronic pouchitis EU		ENTYVIO Target Filing SC UC, CD US; CD Japan
	ALOFISEL ✓ Approved Perianal fistula CD Japan		ALOFISEL Target Filing Perianal Fistulas US
 PLASMA-DERIVED THERAPIES	HYQVIA ✓ Filed HyHub device US	HYQVIA Target Filing CIDP US,EU; MMN EU	
		TAK-880 Target Filing RTU IgG low IgA US, EU	

1. Trial met the pre-specified futility criteria and is being stopped. The data will be shared at a later point in time.

Approved
 Study read-out
 Target Filing
 ✓ Milestone achieved

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GLOSSARY OF ABBREVIATIONS



Regional Abbreviations:

CN: China; EU: Europe; JP: Japan; US: United States of America

AATD	α1-antitrypsin deficiency
ADC	antibody drug conjugate
ADHD	attention deficit hyperactivity disorder
AHA	acquired hemophilia A
ALK	anaplastic lymphoma kinase
ALCL	anaplastic large-cell lymphoma
ALL	acute lymphocytic leukemia
AML	acute myeloid leukemia
ASCT	autologous stem cell transplant
ARD	acid-related diseases
AVA	Advanced Vial Access
BBB	blood brain barrier
BLA	biologics license application
BMA	bradykinin mediated angioedema
BTD	breakthrough therapy designation
CAR-T	chimeric antigen receptor-T
CD	Crohn's disease
CHMP	Committee for Medicinal Products for Human Use
CIDP	chronic inflammatory demyelinating polyradiculoneuropathy
CLL	chronic lymphocytic leukemia
CML	chronic myeloid leukemia
CMV	cytomegalovirus
CNS	central nervous system
CPF	complex perianal fistulas
CRL	complete response letter
CRPC	Castrate-resistant prostate cancer
CTCL	cutaneous T-cell lymphoma
cTTP	congenital thrombotic thrombocytopenic purpura

DEE	developmental and epileptic encephalopathies
DLBCL	diffuse large B-cell lymphoma
DOAC	direct oral anti-coagulation
DS	Dravet syndrome
DU	duodenal ulcer
Dx	Diagnosis
EE H	erosive esophagitis healing
EE M	erosive esophagitis maintenance
EGFR	epidermal growth factor receptor
EMA	European Medicines Agency
FDA	the U.S. Food & Drug Administration
FL	front line
FSI	first subject in
FY	fiscal year
GERD	gastroesophageal reflux disease
GI	gastrointestinal
GU	gastric ulcer
GvHD	graft versus host disease
HAE	hereditary angioedema
H2H	head-to-head
HemA	hemophilia A
HL	Hodgkin lymphoma
HSCT	hematopoietic stem cell transplant
IBD	inflammatory bowel disease
IH	idiopathic hypersomnia
IND	investigational new drug
iNHL	indolent non-Hodgkin's lymphoma
ITP	Immune thrombocytopenic purpura
iTTP	immune thrombotic thrombocytopenic purpura
IV	intravenous
iPSC	induced pluripotent stem cells

L-ASA	low dose aspirin
LSD	lysosomal storage disorder
LCM	lifecycle management
LGS	Lennox-Gastaut syndrome
mAb	monoclonal antibody
MAOB	monoamine oxidase B
MDD	major depressive disorder
MG	myasthenia gravis
MLD	metachromatic leukodystrophy
MM	multiple myeloma
MMN	multifocal motor neuropathy
NBE	New Biological Entity
NCE	New Chemical Entity
ND	newly diagnosed
NDA	new drug application
Neg	Negative
NERD	non-erosive reflux disease
NHL	non-Hodgkin lymphoma
NK	natural killer
NME	new molecular entity
NMPA	National Medical Products Administration
NSCLC	non-small cell lung cancer
NSCT	non stem cell transplant
NT1 or 2	narcolepsy Type 1 or 2
ORR	overall response rate
OSA	obstructive sleep apnea
PARP	poly (ADP-ribose) polymerase
PAS	prior approval supplement
PCAB	potassium competitive acid blocker
PCD	protein C deficiency

PEX	plasma exchange
Ph+ ALL	Philadelphia chromosome-positive acute lymphoblastic leukemia
PID	primary immunodeficiency
PK	pharmacokinetics
PMDA	Japan's Pharmaceuticals and Medical Devices Agency
POC	proof of concept
POGD	post-operative gastrointestinal dysfunction
PONV	postoperative nausea and vomiting
PRIME	Priority medicines scheme by EMA
PTCL	peripheral T-cell lymphoma
PTH	parathyroid hormone
R/R	relapsed/refractory or refractory/resistant
RCC	renal cell cancer
RTK	receptor tyrosine kinase
sALCL	systemic anaplastic large cell lymphoma
SBS	short bowel syndrome
SC	subcutaneous formulation
SCD	sickle cell disease
SCT	stem cell transplant
SID	secondary immunodeficiency
SLE	systemic lupus erythematosus
sq	squamous
STING	stimulator of interferon genes
SUMO	small ubiquitin-related modifier
TESD	treatment emergent sexual dysfunction
TKI	tyrosine kinase inhibitor
UC	ulcerative colitis
vWD	von Willebrand disease
VWF	von Willebrand factor