

Development Pipeline (As of January 31, 2024)

- This table shows clinical studies on indications for which the Sumitomo Pharma Group aims to obtain approval in Japan, U.S., China, or Europe and does not cover all clinical studies.
- The study for the most advanced development stage is listed if there are multiple studies with the same region and indication.
- The development stage is changed when Investigational New Drug Application/amended IND/ Clinical Trial Notification is filed and/or approved by the applicable authority.

1. Psychiatry & Neurology

	Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
Small molecule	SEP-363856 (ulotaront hydrochloride)	Schizophrenia	U.S.	Phase 3
			Japan, China	Phase 2/3
		Adjunctive major depressive disorder (aMDD)	U.S.	Phase 2/3
		Generalized anxiety disorder (GAD)	U.S., Japan	Phase 2/3
	LATUDA® (lurasidone hydrochloride)	(New usage: pediatric) Schizophrenia	U.S.	Phase 2
			Japan	Phase 3
	EPI-589	Parkinson's disease Amyotrophic lateral sclerosis (ALS)	U.S.	Phase 2
			Japan	Phase 2 (Investigator-initiated study)
	SEP-378614	To be determined	U.S.	Phase 1
	SEP-380135	To be determined	U.S.	Phase 1
	DSP-0038	Alzheimer's disease psychosis	U.S.	Phase 1
	DSP-0187	Narcolepsy	Japan	Phase 1
	DSP-3456	Treatment resistant depression	U.S.	Phase 1
	DSP-0378	Dravet syndrome, Lennox-Gastaut syndrome	Japan	Phase 1
DSP-2342	To be determined	U.S.	Phase 1	
Regenerative medicine / cell therapy	CT1-DAP001/ DSP-1083 (Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells)	Parkinson's disease	Japan	Phase 1/2 (Investigator-initiated study)
			U.S.	Phase 1/2 (Investigator-initiated study)
	HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells)	Retinal pigment epithelium tear	Japan	Phase 1/2

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
TP-3654	Myelofibrosis	U.S., Japan	Phase 1/2
DSP-5336	Acute leukemia	U.S., Japan	Phase 1/2
DSP-0390	Glioblastoma	U.S., Japan	Phase 1
TP-1287	Solid tumors	U.S.	Phase 1
TP-1454	Solid tumors	U.S.	Phase 1

3. Others

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
GEMTESA® (vibegron)	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	Phase 3
vibegron	Overactive bladder (OAB)	China	Phase 3
SP-101	Cystic fibrosis	U.S.	Phase 1/2
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections, Hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia	U.S., Japan	Phase 1