

Development Pipeline (As of October 31, 2022)

- 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
SEP-363856 (ulotaront)	Schizophrenia	U.S.	Phase 3
		Japan, China	Phase 2/3 (Global study)
	Adjunctive major depressive disorder (aMDD)	U.S.	Phase 2/3
	Parkinson's disease psychosis	U.S.	Phase 2
SEP-4199	Bipolar I depression	U.S., Japan	Phase 3 (Global study)
LATUDA® (lurasidone hydrochloride)	(New indication) Bipolar I depression	China	Phase 3
	(New usage: pediatric) Schizophrenia	Japan	Phase 3
EPI-589	Parkinson's disease	U.S.	Phase 2
	Amyotrophic lateral sclerosis (ALS)	U.S.	Phase 2
		Japan	Phase 2 (Investigator-initiated study)
SEP-378608	Bipolar disorder	U.S.	Phase 1
DSP-3905	Neuropathic pain	U.S.	Phase 1
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-9632P	Levodopa-induced dyskinesia in Parkinson's disease	Japan	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

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
DSP-0509 (guretolimod)	Solid tumors	U.S., Japan	Phase 1/2
DSP-5336	Acute leukemia	U.S., Japan	Phase 1/2
TP-1287	Solid tumors	U.S.	Phase 1
TP-3654	Myelofibrosis	U.S., Japan	Phase 1/2
TP-1454	Solid tumors	U.S.	Phase 1

DSP-0390	Glioblastoma	U.S., Japan	Phase 1
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3. Regenerative medicine / cell therapy

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
CT1-DAP001/ DSP-1083 (Allo iPS (induced pluripotent stem) cell-derived dopamine neural progenitor)	Parkinson's disease	Japan	Phase 1/2 (Investigator-initiated study)
		U.S.	Preparing to start of clinical study
HLCR011 (Allo iPS cell-derived retinal pigment epithelium)	Age-related macular degeneration (AMD)	Japan	Preparing to start of clinical study

4. Others

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
lefamulin	Bacterial community-acquired pneumonia	China	NDA submitted in October 2021
GEMTESA® (vibegron)	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	Phase 3
rodatristat ethyl	Pulmonary arterial hypertension (PAH)	U.S.	Phase 2
MVT-602	Female infertility	Germany	Phase 2
URO-902	Overactive bladder (OAB)	U.S.	Phase 2
KSP-1007	Complicated urinary tract infections and Complicated intra-abdominal infections	U.S.	Phase 1