

VIII. Development Pipeline (As of July 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/Generic name/Product code		Proposed indication	Region	Development stage
Small molecule	LATUDA®/ lurasidone hydrochloride	(New usage: pediatric) Schizophrenia	Japan	Phase 3
	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	Under preparation for the NDA
			U.S.	Phase 1/2 (Investigator-initiated study)
	Phase 1/2 (Company-sponsored clinical study)			
HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells)	Retinal pigment epithelium tear	Japan	Phase 1/2	

2. Oncology

Brand name/ Generic name/ Product code	Proposed indication	Region	Development stage
nuvisertib/ TP-3654	Myelofibrosis	U.S., Japan	Phase 1/2
enzomenib/ DSP-5336	Acute leukemia	U.S., Japan	Phase 1/2
DSP-0390	Glioblastoma	U.S., Japan	Phase 1
SMP-3124	Solid tumors	U.S., Japan	Phase 1/2

3. Others

Brand name/ Generic name/ Product code	Proposed indication	Region	Development stage
GEMTESA®/ vibegron	(New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH)	U.S.	sNDA submitted in February 2024
vibegron	Overactive bladder (OAB)	China	Phase 3
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
fH1/DSP-0546LP	Influenza	Europe	Phase 1