

Otsuka Group - Pipeline Information

(as of June 30, 2023)

Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status
Psychiatry & Neurology						
OPC-34712/ OPC-34712 FUM <REXULTI / RXULTI>	brexpiprazole	Otsuka Pharmaceutical	D ₂ •5-HT _{1A} partial agonist / 5-HT _{2A} antagonist	Major depressive disorder / Oral	JP	Filed
				Schizophrenia / Oral	China	Filed
				Agitation associated with Alzheimer's dementia / Oral	US	Approved
					JP	Phase III
				Posttraumatic stress disorder / Oral	US	Phase III
				Schizophrenia / Depot injection	US	Phase I
				Schizophrenia / Once-weekly oral	JP	Phase III
aripiprazole long-acting injection <ABILIFY MAINTENA>	aripiprazole	Otsuka Pharmaceutical	D ₂ partial agonist	Schizophrenia / Depot injection	China	Approved
aripiprazole 2-month long-acting injection <ABILIFY ASIMTUFI>	aripiprazole	Otsuka Pharmaceutical	D ₂ partial agonist	Schizophrenia / Depot injection	US	Approved
				Schizophrenia / Depot injection	Europe	Filed
				Bipolar I disorder / Depot injection	US	Approved
OPC-214870		Otsuka Pharmaceutical		Epilepsy / Oral	US	Phase I
AVP-786	deuterium-modified dextromethorphan, quinidine	Avanir	NMDA receptor antagonist / Serotonin and norepinephrine reuptake inhibitor / Sigma-1 receptor agonist	Agitation associated with Alzheimer's dementia / Oral	US, Europe	Phase III
EB-1020	centanafadine	Neurovance	Norepinephrine, dopamine and serotonin reuptake inhibitor	Attention-deficit hyperactivity disorder / Oral	US	Phase III
				Major depressive disorder / Oral	US	Phase II
SEP-363856	ulotaront	Sunovion / PsychoGenics*	TAAR1•5-HT _{1A} agonist	Schizophrenia / Oral	US	Phase III
					JP, China	Phase II / III
				Major depressive disorder / Oral	US	Phase II / III
				Generalized anxiety disorder / Oral	JP, US	Phase II / III
SEP-4199		Sunovion	5-HT ₇ •D ₂ antagonist	Bipolar I depression / Oral	JP, US	Phase III
TAS-205	pizuglanstat	Taiho Pharmaceutical	PGD synthase inhibitor	Duchenne muscular dystrophy / Oral	JP	Phase III

Note: In general, Otsuka discloses clinical trial projects that are in Phase II or later stage of development, however, only clinical trial projects in Phase I conducted with patients are disclosed.
*Sunovion discovered ulotaront (SEP-363856) in collaboration with PsychoGenics.

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Oncology						
ASTX727 <INQOVI>	decitabine, cedazuridine	Astex	DNA methyltransferase inhibitor	Myelodysplastic syndromes / Oral	JP	Phase I
				Acute myeloid leukemia / Oral	Europe	Filed
					US	Phase II
ASTX660	tolinapant	Astex	IAP inhibitor	Solid tumors, Lymphomas / Oral	US	Phase II
				T-cell lymphoma / Oral	JP	Phase I
ASTX660 + ASTX727	tolinapant + decitabine, cedazuridine	Astex		Acute myeloid leukemia / Oral	US	Phase I
				T-cell lymphoma / Oral	US	Phase I
ASTX029		Astex	ERK1/2 inhibitor	Solid tumors / Oral	US	Phase I / II
ASTX295		Astex	MDM2 inhibitor	Solid tumors / Oral	US	Phase I / II
ASTX030	azacitidine, cedazuridine	Astex		Myelodysplastic syndromes / Oral	JP,US	Phase I
AP24534 <ICLUSIG>	ponatinib	Takeda Pharmaceutical	BCR-ABL tyrosine kinase inhibitor	Chronic myeloid leukemia, acute lymphoblastic leukemia / Oral	China	Filed
OPB-111077		Otsuka Pharmaceutical		Diffuse large B-cell lymphoma / Oral	JP	Phase I
				Hematological cancers / Oral	US	Phase I
OPC-415		Osaka University	Activated integrin β7-targeted CAR-T cell therapy	Multiple myeloma / Injection	JP	Phase I / II
TAS-115	pamufetinib	Taiho Pharmaceutical	Multi-kinase inhibitor	Osteosarcoma / Oral	JP	Phase III
				Prostate cancer / Oral	JP	Phase II
TAS-116 <Jeselhy>	pimitespib	Taiho Pharmaceutical	HSP90 inhibitor	Solid tumors / Oral	US, Europe	Phase I
TAS-117		Taiho Pharmaceutical	AKT inhibitor	Solid tumors with germline PTEN mutations / Oral	JP, US, Europe	Phase II
TAS-120 <LYTGObi>	futibatinib	Taiho Pharmaceutical	FGFR inhibitor	Biliary tract cancer / Oral	JP	Approved
				Cholangiocarcinoma / Oral	Europe	Filed
				Breast cancer / Oral	US, Europe	Phase II
				FGFR aberrations cancer / Oral	JP, US, Europe	Phase II
				Urothelial cancer / Oral	US, Europe	Phase II
TAS0313		Taiho Pharmaceutical	Peptide vaccine	Urothelial cancer / Injection	JP	Phase II
TAS0728		Taiho Pharmaceutical		Solid tumors / Oral	US, Europe	Phase I / II
TAS0953		Taiho Pharmaceutical		Solid tumors / Oral	JP	Phase I / II
TAS3351		Taiho Pharmaceutical		Non-small cell lung cancer / Oral	JP, US, Europe	Phase I / II
TAS0612		Taiho Pharmaceutical		Solid tumors / Oral	US, Europe	Phase I
TAS1440		Taiho Pharmaceutical		Acute myeloid leukemia / Oral	US	Phase I
TAS1553		Taiho Pharmaceutical		Acute myeloid leukemia / Oral	US	Phase I
TAS2940		Taiho Pharmaceutical		Solid tumors / Oral	US, Europe	Phase I
TAS3681		Taiho Pharmaceutical		Prostate cancer / Oral	US, Europe	Phase I
TAS6417	zipalertinib	Taiho Pharmaceutical	EGFR inhibitor	Non-small cell lung cancer / Oral	US, Europe	Phase I / II
AB122	zimberelimab	Arcus		Solid tumors / Injection	JP	Phase I
AB122 + TAS-115	zimberelimab + pamufetinib	Arcus / Taiho Pharmaceutical		Solid tumors / Injection + oral	JP	Phase I
AB122 + TAS-116	zimberelimab + pimitespib	Arcus / Taiho Pharmaceutical		Solid tumors / Injection + oral	JP	Phase I
AB122 + TAS-120	zimberelimab + futibatinib	Arcus / Taiho Pharmaceutical		Solid tumors / Injection + oral	JP	Phase I
AB122 + AB154	zimberelimab + domvanalimab	Arcus	Anti-PD-1 antibody + anti-TIGIT antibody	Upper gastrointestinal tract cancer / Injection	JP	Phase III
				Non-small cell lung cancer / Injection	JP	Phase I
ET-743 <Yondelis>	trabectedin	Pharma Mar		Ovarian cancer / Injection	JP	Phase I

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Cardiovascular & Renal system						
VIS649	sibeprenlimab	Visterra	Anti-APRIL monoclonal antibody	IgA nephropathy / Injection	JP, US, Europe	Phase III
ETC-1002	bempedoic acid	Esperion	ATP-citrate lyase inhibitor	Hypercholesterolemia / Oral	JP	Phase III
OPC-131461		Otsuka Pharmaceutical	V _{1a} /V ₂ dual antagonist	Cardiac edema / Oral	JP	Phase II
NO-13065		Otsuka Pharmaceutical Factory		Obesity / Oral	US	Phase I
Other areas						
TAS-303		Taiho Pharmaceutical	Selective noradrenaline reuptake inhibitor	Stress urinary incontinence / Oral	JP	Phase II
TAC-302		Meiji		Detrusor underactivity with overactive bladder / Oral	JP	Phase II
TAS-115	pamufetinib	Taiho Pharmaceutical	Multi-kinase inhibitor	Chronic fibrosing interstitial lung diseases with a progressive phenotype / Oral	JP	Phase II
TAS5315		Taiho Pharmaceutical	BTK inhibitor	Rheumatoid arthritis / Oral	JP	Phase II
				Chronic spontaneous urticaria / Oral	JP	Phase II
OPC-67683 <Delyba>	delamanid	Otsuka Pharmaceutical	Mycolic acid biosynthesis inhibitor	Multidrug-resistant tuberculosis / Oral	US	Phase III
OPC-167832	quabodepistat	Otsuka Pharmaceutical	DprE1 inhibitor	Tuberculosis / Oral	US	Phase II
OPA-15406 <Moizerto>	difamilast	Otsuka Pharmaceutical	PDE4 inhibitor	Atopic dermatitis / Ointment	China	Phase III
OPC-1085EL <Mikeluna>	carteolol, latanoprost	Otsuka Pharmaceutical	β receptor antagonist / PGF2α analogue	Glaucoma, ocular hypertension / Eye drops	China	Phase III
OPS-2071		Otsuka Pharmaceutical	DNA gyrase inhibitor	Irritable Bowel Syndrome / Oral	China	Phase II
VIS171		Visterra	Modified interleukin-2 molecule designed to specifically activate and amplify regulatory T lymphocytes	Autoimmune disease / Injection	TBD	Phase I
OPF-109	glucose, electrolyte, amino acid, vitamin	Otsuka Pharmaceutical Factory		High calorie parenteral nutrition for chronic renal failure / Injection	JP	Phase III

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Otsuka Group - Pipeline Information

<Changes in Pipeline Information Since March 31, 2023>

Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status	Change from 1Q FY2023
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Psychiatry & Neurology

OPC-34712 <REXULTI>	brexpiprazole	Otsuka Pharmaceutical	D ₂ •5-HT _{1A} partial agonist / 5-HT _{2A} antagonist	Agitation associated with Alzheimer's dementia / Oral	US	Approved	Filed → Approved
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				Bipolar I disorder / Depot injection	US	Approved	Filed → Approved

Oncology

TAS-120 <LYTGOBI>	futibatinib	Taiho Pharmaceutical	FGFR inhibitor	Biliary tract cancer / Oral	JP	Approved	Filed → Approved
TAS3351		Taiho Pharmaceutical		Non-small cell lung cancer / Oral	JP, US, Europe	Phase I / II	Added
AB122 + AB154	zimberelimab + domvanalimab	Arcus	Anti-PD-1 antibody + anti-TIGIT antibody	Upper gastrointestinal tract cancer / Injection	JP	Phase III	Added
				Non-small cell lung cancer / Injection	JP	Phase I	Added

Other areas

OPS-2071		Otsuka Pharmaceutical	DNA gyrase inhibitor	Irritable Bowel Syndrome / Oral	China	Phase II	Added
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<Changes in Pipeline Information Since July 1, 2023>

Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status	Change from July 1, 2023
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TAS-120 <LYTGOBI>	futibatinib	Taiho Pharmaceutical	FGFR inhibitor	Cholangiocarcinoma / Oral	Europe	Filed	Filed → Approved
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