

Otsuka Group - Pipeline Information

(as of June 30, 2021)

Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status
Psychiatry & Neurology						
OPC-34712 <REXULTI / RXULTI>	brexpiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Major depressive disorder / Oral	JP, Europe	Phase III
				Schizophrenia / Oral	China	Phase III
				Agitation associated with dementia of the Alzheimer's type / Oral	JP, US, Europe	Phase III
				Posttraumatic stress disorder / Oral	US	Phase III
				Borderline personality disorder / Oral	US	Phase II
				Schizophrenia / Depot injection	US	Phase I
aripiprazole long-acting injection	aripiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Schizophrenia / Depot injection	China	Filed
OPC-64005		Otsuka Pharmaceutical	Serotonin, norepinephrine and dopamine reuptake inhibitor	Major depressive disorder / Oral	JP	Phase II
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 dementia of the Alzheimer's type / Oral	US, Europe	Phase III
				Negative symptoms of schizophrenia / Oral	US	Phase II / III
				Traumatic brain injury / Oral	US	Phase II
				Intermittent explosive disorder / Oral	US	Phase II
EB-1020	centanafadine	Neurovance	Norepinephrine, dopamine and serotonin reuptake inhibitor	Attention-deficit hyperactivity disorder / Oral	US	Phase III
TAS-205	pizuglanstat	Taiho Pharmaceutical	PGD synthase inhibitor	Duchenne muscular dystrophy / Oral	JP	Phase III
TEV-48125 <AJOVY>	fremanezumab	Teva	Anti-CGRP antibody	Migraine / Injection	JP	Approved

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Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status
Oncology						
ASTX727 <INQOVI>	decitabine, cedazuridine	Astex	DNA methyltransferase inhibitor	Myelodysplastic syndromes / Oral	JP	Phase I
				Acute myeloid leukemia / Oral	Europe	Phase III
				Acute myeloid leukemia / Oral	US	Phase I
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
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, Philadelphia chromosome-positive acute lymphoblastic leukemia / Oral	China	Phase II
OPB-111077		Otsuka Pharmaceutical		Diffuse large B-cell lymphoma / Oral	JP	Phase I
				Hematological cancers / Oral	US	Phase I
OPB-171775		Otsuka Pharmaceutical		Solid tumors / Oral	JP	Phase I
TAS-114		Taiho Pharmaceutical	dUTPase inhibitor	Non-small cell lung cancer / Oral	JP, US, Europe	Phase II
TAS-115	pamufetinib	Taiho Pharmaceutical	Multi-kinase inhibitor	Osteosarcoma / Oral	JP	Phase III
				Prostate cancer / Oral	JP	Phase II
TAS-116	pimitespib	Taiho Pharmaceutical	HSP90 inhibitor	Gastrointestinal stromal tumor / Oral	JP	Phase III
				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	futibatinib	Taiho Pharmaceutical	FGFR inhibitor	Cholangiocarcinoma / Oral	JP, US, Europe	Phase III
				Breast cancer / Oral	US, Europe	Phase II
				FGFR aberrations cancer / Oral	JP, US, Europe	Phase II
				Urothelial cancer / Injection	US, Europe	Phase II
TAS0313		Taiho Pharmaceutical	Peptide vaccine	Urothelial cancer / Injection	JP	Phase II
TAS3681		Taiho Pharmaceutical		Prostate cancer / Oral	US, Europe	Phase I
TAS0728		Taiho Pharmaceutical		Solid tumors / Oral	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
TAS0953		Taiho Pharmaceutical		Solid tumors / Oral	JP	Phase I / II
ET-743 <Yondelis>	trabectedin	PharmaMar		Ovarian cancer / Injection	JP	Phase I
TBI-1401	canerpaturev	Takara Bio	Oncolytic virus	Pancreatic cancer / Injection	JP	Phase I
TBI-1301	mipetresgene autoleucl	Takara Bio	NY-ESO-1 siTCR™ gene therapies	Synovial sarcoma / Injection	JP	Phase I / II
TBI-1501		Takara Bio	CD19-CAR gene therapies	Acute lymphoblastic leukemia / Injection	JP	Phase I / II
Pro-NETU	fosnetupitant	Helsinn Healthcare	NK ₁ receptor antagonist	Chemotherapy-induced nausea and vomiting / Injection	JP	Filed

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Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status
Cardiovascular & Renal system						
OPC-61815	tolvaptan sodium phosphate	Otsuka Pharmaceutical	V ₂ -receptor antagonist	Cardiac edema / Injection	JP	Filed
AKB-6548	vadadustat	Akebia	HIF-prolyl hydroxylase inhibitor	Anemia associated with chronic kidney disease / Oral	US	Filed
					Europe	Phase III
VIS649		Visterra	Anti-APRIL monoclonal antibody	IgA nephropathy / Injection	JP, US, Europe	Phase II
ETC-1002	bempedoic acid	Esperion	ATP-citrate lyase	Hypercholesterolemia / Oral	JP	Phase II
	voclosporin	Aurinia	Calcineurin inhibitor	Lupus nephritis / Oral	Europe	Filed
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	Idiopathic pulmonary fibrosis / Oral	JP	Phase II
TAS5315		Taiho Pharmaceutical	BTK inhibitor	Rheumatoid arthritis / Oral	JP	Phase II
OPC-67683 <Delyba>	delamanid	Otsuka Pharmaceutical	Mycolic acid biosynthesis inhibitor	Multidrug-resistant tuberculosis / Oral	US	Phase III
OPC-167832		Otsuka Pharmaceutical	DPrE1 inhibitor	Tuberculosis / Oral	US	Phase I / II
OPF-109	glucose, electrolyte, amino acid, vitamin	Otsuka Pharmaceutical Factory		High calorie parenteral nutrition for chronic renal failure / Injection	JP	Phase III
NO-13065		Otsuka Pharmaceutical Factory		Obesity / Oral	US	Phase I
OPA-15406	difamilast	Otsuka Pharmaceutical	PDE4 inhibitor	Atopic dermatitis / Ointment	JP	Filed

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Otsuka Group - Pipeline Information

<Changes in Pipeline Information Since March 31, 2021>

Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status	Change from 1Q FY2021
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Psychiatry & Neurology

TEV-48125 <AJOVY>	fremanezumab	Teva	Anti-CGRP antibody	Migraine / Injection	JP	Approved	Filed→Approved
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Oncology

TAS-117		Taiho Pharmaceutical	AKT inhibitor	Solid tumors with germline PTEN mutations / Oral	JP, US, Europe	Phase II	Added
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Cardiovascular & Renal system

	voclosporin	Aurinia	Calcineurin inhibitor	Lupus nephritis / Oral	Europe	Filed	Phase III→Filed
ETC-1002	bempedoic acid	Esperion	ATP-citrate lyase	Hypercholesterolemia / Oral	JP	Phase II	Phase I→Phase II

Other areas

NO-13065		Otsuka Pharmaceutical Factory		Obesity / Oral	US	Phase I	Added
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