

Otsuka Group - Pipeline Information

(as of December 31, 2018)

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, EU, Asia	Phase III
				Agitation associated with dementia of the Alzheimer's type / Oral	JP, US, EU	Phase III
				Bipolar I disorder / Oral	US, EU	Phase III
				Posttraumatic stress disorder / Oral	US, EU	Phase II
				Schizophrenia / Depot injection	US	Phase I
OPC-64005		Otsuka Pharmaceutical	Serotonin, norepinephrine and dopamine reuptake inhibitor	Attention deficit hyperactivity disorder / Oral	US	Phase II
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, EU	Phase III
				Negative symptoms of schizophrenia / Oral	US	Phase II
				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 II
TAS-205		Taiho Pharmaceutical	PGD synthase inhibitor	Duchenne muscular dystrophy / Oral	JP	Phase II
Lu AA36143	nalmefene	Lundbeck	Opioid receptor antagonist	Alcohol dependence / Oral	JP	Approved*
Lu AF20513		Lundbeck	β -amyloid vaccine	Alzheimer's demetia / Injection	EU	Phase I
TEV-48125	fremanezumab	Teva	Anti-CGRP antibody	Migraine / Injection	JP	Phase II / III

Note: In general, Otsuka disclose compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.

* Event after January 1, 2019

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Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status
Oncology						
TAS-102 <LONSURF>	trifluridine, tipiracil	Taiho Pharmaceutical	Interference with the function of DNA	Colorectal cancer / Oral	Asia	Filed
				Gastric cancer / Oral	JP, US, EU	Filed
TAS-118	tegafur, gimeracil, oteracil, folinate	Taiho Pharmaceutical	Anti-metabolite	Gastric cancer / Oral	JP, Asia	Phase III
SGI-110	guadecitabine	Astex	DNA methyltransferase inhibitor	Ovarian cancer / Injection	US, EU	Phase II
				Acute myeloid leukemia / Injection	JP, US, EU Asia	Phase III
				Myelodysplastic syndrome / Injection	JP, US, EU Asia	Phase III
ASTX727		Astex	DNA methyltransferase inhibitor	Myelodysplastic syndrome / Oral	US	Phase III
ASTX660		Astex	IAP inhibitor	Solid tumors, Lymphomas / Oral	US	Phase II
ASTX029		Astex		Solid tumors / Oral	US	Phase I
OPB-111077		Otsuka Pharmaceutical		Solid tumors, Hematological cancers / Oral	US, Asia	Phase I
TAS-114		Taiho Pharmaceutical	dUTPase inhibitor	Non-small cell lung cancer / Oral	JP, US, EU	Phase II
TAS-115		Taiho Pharmaceutical	Multi-kinase inhibitor	Prostate cancer / Oral	JP	Phase II
TAS-116		Taiho Pharmaceutical	HSP90 inhibitor	Gastrointestinal stromal tumor / Oral	JP	Phase III
				Solid tumors / Oral	US, EU	Phase I
TAS-117		Taiho Pharmaceutical		Solid tumors / Oral	JP	Phase I
TAS-119		Taiho Pharmaceutical		Solid tumors / Oral	US, EU	Phase I
TAS-120		Taiho Pharmaceutical	FGFR inhibitor	Cholangiocarcinoma / Oral	JP, US, EU	Phase II
TAS0313		Taiho Pharmaceutical		Solid tumors / Injection	JP	Phase I / II
TAS3681		Taiho Pharmaceutical		Prostate cancer / Oral	US, EU	Phase I
TAS4464		Taiho Pharmaceutical		Solid tumors, Hematological cancers / Injection	JP, US, EU	Phase I
TAS0728		Taiho Pharmaceutical		Solid tumors / Oral	US, EU	Phase I / II
ET-743	trabectedin	PharmaMar		Ovarian cancer / Injection	JP	Phase I
TBI-1401	canerpaturev	Takara Bio	Oncolytic Virus	Melanoma / Injection	JP	Phase II
				Pancreatic cancer / Injection	JP	Phase I
TBI-1301		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	Phase II

Note: In general, Otsuka disclose compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.

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Cardiovascular & Renal system						
OPC-41061 <Samsca>	tolvaptan	Otsuka Pharmaceutical	V ₂ receptor antagonist	Syndrome of inappropriate antidiuretic hormone secretion / Oral	JP	Phase III
AKB-6548	vadadustat	Akebia	HIF-prolyl hydroxylase inhibitor	Anemia associated with chronic kidney disease / Oral	US, EU	Phase III
OPC-61815		Otsuka Pharmaceutical	V ₂ receptor antagonist	Cardiac edema / Injection	JP	Phase II
Other areas						
TAS-303		Taiho Pharmaceutical	Selective norepinephrine reuptake inhibitor	Stress urinary incontinence / Oral	JP	Phase II
TAC-302		Meiji		Detrusor underactivity with overactive bladder/ Oral	JP	Phase II
TAS-115		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	Dpr-E1 inhibitor	Tuberculosis / Oral	US	Phase I / II
OPF-105	Glucose, electrolyte, amino acid, fat and vitamin	Otsuka Pharmaceutical Factory		Peripheral parenteral nutrition / Injection	JP	Phase III
OPA-15406		Otsuka Pharmaceutical	PDE4 inhibitor	Atopic dermatitis / Ointment	JP	Phase II
OPS-2071		Otsuka Pharmaceutical	New quinolone based antibacterial agent	Clostridium difficile infection, enteric infection / Oral	JP, Asia	Phase II
VIS410		Visterra	Anti-hemagglutinin monoclonal antibody	Influenza A infection	US	Phase II
Diagnostics						
C13-CAC		Otsuka Pharmaceutical	13C-calcium carbonate breath test	Measurement of gastric acidity / In-vivo diagnostic agent	JP	Phase II
ODK-1003-CN		Otsuka Pharmaceutical	WT1 mRNA RT-PCR assay kit	Diagnosis for Myelodysplastic syndrome / In-vitro diagnostic agent	Asia	Filed

Note: In general, Otsuka disclose compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.

OPC-67683 (Indication: Multidrug-resistant tuberculosis for pediatrics) and OPC-12759E (Indication: Dry eyes) were deleted from list due to the change of criteria for disclose: programs for new formulation or pediatric indication are excluded from the coverage.

Otsuka Group - Pipeline Information

<Changes in Pipeline Information Since September 30, 2018>

Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status	Change from 3Q FY2018
Oncology							
TAS-102 <LONSURF>	trifluridine, tipiracil	Taiho Pharmaceutical	Interference with the function of DNA	Gastric cancer / Oral	US, EU	Filed	Phase III → Filed
TAS-116		Taiho Pharmaceutical	HSP90 inhibitor	Gastrointestinal stromal tumor / Oral	JP	Phase III	Phase II → Phase III
Other areas							
OPC-167832		Otsuka Pharmaceutical	Dpr-E1 inhibitor	Tuberculosis / Oral	US	Phase I / II	Added

<Event after January 1, 2019>

Code / <Brand name>	Generic name	Origin	Features	Indication / Dosage form	Country / Region	Development status	Change from 3Q FY2018
Lu AA36143	nalmefene	Lundbeck	Opioid receptor antagonist	Alcohol dependence / Oral	JP	Approved	Filed → Approved