PHARMACODIA GLOBAL WEEKLY DRUG R&D PROGRESS REPORT

INNOVATIVE DRUGS

REPORT No. GID-2025/08/I

DATE: 02-08-2025 TO 08-08-2025

Contents

1、Global Drug Approval/R&D Trends

1.1 Global Novel Drug Approval Status

1.1.1 NDA Approval

Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Dordaviprone	Jazz Pharmaceuticals	ERK1; AKT1; ERK2; DRD2; ClpP	Adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy	Approved	FDA-accelerated approval	2025.08.06
Zongertinib	Boehringer Ingelheim	HER2; HER2 exon 20 insert mutations	Adults with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) who have received systemic treatment and have been found to carry HER2 tyrosine kinase domain (TKD) activating mutations as detected by FDA-approved tests	Approved	FDA-accelerated approval	2025.08.08

Data source：Pharmacodia Global

1.1.2 BLA Approval

No drugs have been approved this week.

1.1.3 Vaccine Approval

No drugs have been approved this week.

1.1.4 New Combination Therapy Approval

No drugs have been approved this week.

1.1.5 Expanded Indication Approval

Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Fremanezumab	Teva	CGRP	Paroxysmal migraine in	Approved	FDA-approval	2025.08.06

	children and adolescents aged 6 to 17 who weigh 45 kilograms (99 pounds) or more		of extended indication

Data source: Pharmacodia Global

1.1.6 New Formulation Approval

No drugs have been approved this week.

1.2 Global Novel Drug Application Status

1.2.1 NDA/BLA

Drugs Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Vaccine	Chikungunya virus vaccine(Valneva)	Valneva	Not applicable	Prevention of disease caused by Chikungunya Virus (CHIKV) in individuals aged in 18 years and older who are at high risk of exposure to CHIKV	Approved	FDA-positive feedback	2025.08.07

Data source: Pharmacodia Global

1.2.2 Special Designations

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Birelentinib	Dizal	LYN; BTK	Adults with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) who have received at least two lines of treatment (including BTK inhibitors and BCL-	Phase II	FDA-Fast Track Designation	2025.08.06

				2 inhibitors) in the past			
Biologicals	CMTX-101	Clarametyx Biosciences	DNA-binding proteins	Cystic fibrosis affected by chronic bacterial pulmonary infection	Phase II	FDA-Fast Track Designation	2025.08.04
	CMTX-101	Clarametyx Biosciences	DNA-binding proteins	Cystic fibrosis affected by chronic bacterial pulmonary infection	Phase II	FDA-Qualified Infectious Disease Product (QIDP) designation	2025.08.04
	DYNE-251	Dyne Therapeutics	TfR1; DMD	Duchenne muscular dystrophy (DMD)	Phase II	FDA-Breakthrough Therapy Designation	2025.08.04
	Trastuzumab rezetecan	Hengrui	HER2; TOP1	Gastric cancer or adenocarcinoma of the gastroesophageal junction	Approved	FDA-Orphan Drug Designation	2025.08.06
Cell Therapy	GLPG-5101	Galapagos	CD19	Relapsed/Refractory Mantle Cell Lymphoma (R/R MCL)	Phase II	FDA-Regenerative Medicine Advanced Therapy (RMAT) Designation	2025.08.06

Data source：Pharmacodia Global

1.3 Global Novel Drug R&D Status

1.3.1 Oncology

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	ATV-1601	Atavistik	AKT1	AKT1E17K mutant solid tumors in adults	Phase I	First patient dosed in phase I trial	2025.08.04
	Lenvatinib Mesylate	Merck	VEGFR1; KIT; VEGFR3; FGFR4;	Esophageal cancer	Approved	Terminated the deveopment of phase III	2025.08.05

			FGFR1; FGFR3; FGFR2; VEGFR2; PDGFR-α; RET			trial	
	Vepdegestrant	Pfizer	ERs	Second-line treatment with the CDK4/6 inhibitor Palbociclib for ER+/HER2- advanced or metastatic breast cancer	NDA	Terminated the deveopment of phase II trial	2025.08.05
	Vepdegestrant	Pfizer	ERs	Combined with the investigational CDK4 inhibitor Atirmociclib for first-line treatment of ER+/HER2- advanced or metastatic breast cancer	NDA	Terminated the deveopment of phase II trial	2025.08.05
	Annamycin liposomal (Moleculin Biotech)	Moleculin	TOP2	Various primary and metastatic liver cancers, including hepatocellular carcinoma (HCC), colorectal liver metastases and pancreatic ductal adenocarcinoma (PDAC) liver metastases	Phase III	Presented positive data of preclinical	2025.08.06
	Mitomycin sustained release (UroGen Pharma)	UroGen Pharma	DNA	Recurrent low-grade moderate-risk non-muscle-invasive bladder cancer (LG-IR-NMIBC) in adults	Approved	Presented positive data of phase III trial	2025.08.06
	TELOMIR-1	Telomir	Telomerase	Aggressive prostate cancer	Preclinical	Presented positive data of preclinical	2025.08.07
Biologicals	Izalontama	Baili-pharm	EGFR;	Egfr-tki-resistant	Phase III	Initiated	2025.08.03

	b brengitecan		HER3; TOP1	EGFR-mutated non-small cell lung cancer		phase II/III trial	
	Eftilagimod alpha	Immutep	Histocompatibility antigens class II	Recurrent/metastatic head and neck squamous cell carcinoma (1L HNSCC) with PD-L1 expression lower than 1(combined positive score [CPS]<1)	Phase III	FDA-positive feedback	2025.08.05
	Emactuzumab	SynOx Therapeutics	CSF1R	Giant cell tumor of the ganglion sheath (TGCT) that is inoperable or does not benefit from surgery	Phase III	Completed the enrollment of phase III trial	2025.08.05
	Quavonlimab	Merck	CTLA4	Non-small cell lung cancer	Phase II	Terminated the deveopment of phase II trial	2025.08.05
	Patritumab Deruxtecan	Merck	HER3; TOP1	Non-small cell lung cancer	BLA	Terminated the deveopment of phase III trial	2025.08.05
	Felmetatug vedotin	Pfizer	Tubulin; VTCN1	Advanced solid tumors	Phase I	Terminated the deveopment of phase I trial	2025.08.05
	Izalontamab brengitecan	Baili-pharm	EGFR; HER3; TOP1	Metastatic urothelial carcinoma	Phase III	Initiated phase II/III trial	2025.08.06
Cell Therapy	INKmune	Inmune	Not applicable	Metastatic castration-resistant prostate cancer (mCRPC)	Phase II	Presented positive data of phase I/II trial	2025.08.04
Vaccine	ELI-002	Elicio	KRAS	Mutant KRAS (mKRAS) -driven pancreatic ductal	Phase II	IDMC-positive feedback	2025.08.05

				adenocarcinoma (PDAC)			

Data source: Pharmacodia Global

1.3.2 Hematology and Lymph Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Roxadustat	FibroGen	HIF-PHs	Anemia in patients with LR-MDS and high RBC transfusion burden	Approved	FDA-positive type C meeting feedback	2025.08.07
Biologicals	Epcoritamab	Genmab	CD20; CD3	Adult relapsed or refractory (R/R) follicular lymphoma (FL)	Approved	Presented positive data of phase III trial	2025.08.07
Cell Therapy	SENTI-202	Senti Biosciences	FLT3; CD33	Recurrent/refractory hematological malignancies, including acute myeloid leukemia (AML)	Phase I	Presented positive data of phase I trial	2025.08.05
Vaccine	Galinpepimut-S	Sellas	Not applicable	Acute myeloid leukemia (AML)	Phase III	IDMC-positive feedback	2025.08.07

Data source: Pharmacodia Global

1.3.3 Pathological Conditions, Signs and Symptoms

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	SB-01 (Ensol BioSciences)	Spine	TGF-β1	Chronic low back pain (CLBP) related to degenerative disc disease (DDD)	Phase III	Presented negative data of phase III trial	2025.08.01
	VX-993	Vertex	Nav1.8	Acute pain after bunion resection	Phase II	Presented negative data of phase II trial	2025.08.04
	Mazisotine	Lilly	SSTR4	Pain	Phase II	Terminated the deveopment of phase II	2025.08.05

						trial	
	MAX-001(Maxona Pharmaceuticals)	Maxona	SERT; DAT; NET	Acute pain	Phase I	Submitted IND to FDA	2025.08.07

Data source: Pharmacodia Global

1.3.4 Mental Disorders

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Nelivaptan	HMNC	V1bR	Major Depressive Disorder (MDD)	Phase II	Presented positive data of phase IIb trial	2025.08.05
	Extended Release Naltrexone Implant (Akyso)	Akyso	Opioid receptors	Opioid use disorder (OUD)	Phase I	Completed phase Ia trial	2025.08.05
	Dexmedetomidine Hydrochloride (BioXcel Therapeutics)	BioXcel Therapeutics	ADRA2	Chronic stress-induced behaviors	Approved	Presented positive data of phase III trial	2025.08.06
	Deuterated psilocybin analog	Cybin	5-HT2A; 5-HT1A	Major depressive disorder	Phase III	Irish Medicines Board-approved phase III trial	2025.08.07
Digital Therapeutics	CT-155	Boehringer; Click Therapeutics	Updating	People diagnosed and living with schizophrenia experiencing negative symptoms	Phase III	Presented positive data of phase III trial	2025.08.07

Data source: Pharmacodia Global

1.3.5 Nervous System Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Sumifilam	Cassava	FLN-A	Tuberculous	Phase III	Presented	2025.08.04

		Sciences		sclerosis complex (TSC) -related epilepsy		positive data of preclinical	
Cell Therapy	OPC-1 (Geron)	Lineage	Not applicable	Subacute and chronic spinal cord injuries	No progression (Phase II)	First patient dosed in phase I trial	2025.08.04

Data source: Pharmacodia Global

1.3.6 Infections

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	AIC-468	AiCuris Anti-infective Cures	Updating	BK virus (BKV) infection in kidney transplant recipients	Phase I	Presented positive data of phase I trial	2025.08.05
	ABI-6250	Assembly Biosciences	NTCP	Hepatitis D Virus (HDV)	Phase I	Presented positive data of phase Ia trial	2025.08.06
	ProLectin-M	BioXyTran	Gal-3	Respiratory tract infection	Phase II	Completed dosing in the dose optimization clinical trial	2025.08.07
	ABI-5366	Assembly Biosciences	DNAhelicase/primasecomplex	Recurrent genital herpes	Phase I	Presented positive data of phase Ib trial	2025.08.08
Vaccine	PF-6425090	Pfizer	Not applicable	Primary Clostridioides difficile infection	Phase III	Terminated the deveopment of phase I trial	2025.08.05

Data source: Pharmacodia Global

1.3.7 Nutritional and Metabolic Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Exenatide implant (Vivani Medical)	Vivani	GLP1R	Obesity and overweight	Phase I	Presented positive data of phase I trial	2025.08.05

	IBI-3032	Innovent	GLP1R	Overweight or obese	Phase I	FDA-approved IND	2025.08.05
	NNC0519-0130	Novo Nordisk	GIPR	Overweight or obese	Phase II	Terminated the deveopment of phase II trial	2025.08.05
	INV-347	Novo Nordisk	CB1	Overweight or obese	Phase I	Terminated the deveopment of phase I trial	2025.08.05
	Orforglipron	Lilly	GLP1R	Adults who are obese or overweight but without diabetes with at least one weight-related comorbidity	Phase III	presented positive topline data of phase III trial	2025.08.07
Biologicals	Semaglutide	Novo Nordisk	GLP1R	Overweight or obesity	Approved	Presented positive data of phase IIIa trial	2025.08.10

Data source: Pharmacodia Global

1.3.8 Eyes Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	NCX-470	NicOx	Prostanoid receptor	Ocular hypertension	Phase III	Initiated phase III trial	2025.08.05
	PA-5108	Polyactiva	Updating	Primary open-angle glaucoma (POAG); Ocular hypertension (OHT)	Phase II	First patient enrolled in phase IIb trial	2025.08.07

Data source: Pharmacodia Global

1.3.9 Skin and Connective Tissue Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date

Chemicals	LY-3972406	Lilly	KCNA3	Psoriasis	Phase II	Terminated the deveopment of phase II trial	2025.08.05
	TolaSure Topical Gel	Biomendics	Intermediate filament proteins	Patients with generalized intermediate to severe Epidermolysis Bullosa Simplex (EB Simplex)	Phase II	Initiated phase II trial	2025.08.08

Data source: Pharmacodia Global

1.3.10 Immune System Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Itaconate mimetic	Lilly	Updating	Autoimmune and inflammatory disease	Phase I	Terminated the deveopment of phase I trial	2025.08.05
Biologicals	PT-101	Merck	IL2RA	Matosus and vitiligo	Phase II	Terminated the deveopment of phase II trial	2025.08.05
	Tegoprubart	Eledon	CD40L	Kidney transplant rejection reaction	Phase II	Presented positive data of phase Ib trial	2025.08.06

Data source: Pharmacodia Global

1.3.11 Endocrinology Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Cadisegliatin	Vtv Therapeutics	GK	Type I diabetes (TID)	Phase III	First patient enrolled in phase III trial	2025.08.07
Cell Therapy	PTG-007	PolTREG	Not applicable	Children with type Children with type I diabetes	Phase II	First patient dosed in phase II trial	2025.08.04
	UP-421	Sana	HLA	Type I diabetes	Phase I	Presented	2025.08.06

				(TID)		positive data of clinica trial	

Data source: Pharmacodia Global

1.3.12 Cardiovascular Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Inclisiran sodium	Novartis	PCSK9	Acute Coronary Syndrome (ACS)	Approved	Initiated phase III trial	2025.08.04
	Istaroxime	Windtree	Na+/K+ ATPase	Cardiogenic shock	Phase II	Presented positive data of phase II trial	2025.08.05
Biologicals	MAR001	Marea Therapeutics	ANGPTL4	Atherosclerotic cardiovascular disease (ASCVD) in adults	Phase II	First patient enrolled in phase IIb trial	2025.08.04
	ABCL-635	AbCellera	NK3R	Moderate to severe vasomotor symptoms (VMS) related to menopause	Phase I	First patient dosed in phase I trial	2025.08.07

Data source: Pharmacodia Global

1.3.13 Gastroenterology Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	LY-3885125	Lilly	SCAP	Metabolic dysfunction-related fatty liver disease (MASLD)	Terminated (Phase I)	Terminated the deveopment of phase I trial	2025.08.05
	Tegoprazan	Sebela Pharmaceuticals	H+/K+ ATPase	Gastroesophageal reflux disease (GERD)	Approved	Presented positive topline data of phase III trial	2025.08.07
	GT-2108	Palisade Bio	PDE4	Moderate to severe ulcerative colitis (UC)	Phase I	Presented positive data of phase Ia trial	2025.08.07

	GT-2108	Palisade Bio	PDE4	Moderate to severe ulcerative colitis (UC)	Phase I	Presented positive data of phase Ib trial	2025.08.07

Data source：Pharmacodia Global

1.3.14 Urogenital Diseases

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Metablok	Arch Biopartners	DPEP1	Cardiac surgery associated acute kidney injury (CS-AKI)	Phase II	First patient dosed in phase II trial	2025.08.06
Biologicals	PS-002 (Purespring Therapeutics)	Purespring	Updating	IgA nephropathy (IgAN)	Phase II	MHRA-approved I/II phase trial	2025.08.05
	E-602	Palleon	Updating	Active glomerulonephritis	Phase II	First patient dosed in phase II trial	2025.08.07

Data source：Pharmacodia Global

2、Drug Approval/R&D Trends in China

2.1 Novel Drug Approval Status in China

2.1.1 NDA Approval

No drugs have been approved this week.

2.1.2 BLA Approval

Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Dulaglutide Biosimilar (Luye Pharma)	Boan-bio	GLP1R	Blood glucose control in adult patients with type II diabetes	Approved	NMPA-approved	2025.08.05
Adalimumab biosimilar (Wuhan Institute Of Biological)	Wuhan Institute Of Biological	TNFα	Rheumatoid arthritis; Ankylosing spondylitis; Psoriasis; Crohn's disease; Uveitis; Polyarticular juvenile idiopathic arthritis;	Approved	NMPA-Approved	2025.08.05

			Childhood plaque psoriasis			

Data source: Pharmacodia Global

2.1.3 Vaccine Approval

No drugs have been approved this week.

2.1.4 New Compound Approval

No drugs have been approved this week.

2.1.5 Expanded Indication Approval

Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Benralizumab	AstraZeneca	IL5RA	Maintenance treatment for severe eosinophilic asthma (SEA) in children (6 to < 12 years old)	Approved	NMPA-approval of extended indication	2025.08.04
Amivantamab	Johnson & Johnson	c-Met; EGFR	First-line treatment for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R replacement mutation	Approved	NMPA-approval of extended indication	2025.08.08

Data source: Pharmacodia Global

2.1.6 New Formulation Approval

No drugs have been approved this week.

2.1.7 Refusal of Approval

No drugs have been approved this week.

2.2 New Drug Application Status in China

2.2.1 NDA/BLA

Drug Type	Drug Name	Company	Target	Application Type	Registration classification	Acceptance number	Date
Chemicals	Deunoxavir Marboxil	Jiaxing AnDiCon Biotech Co Ltd; Shanghai STA Pharmaceutical Product Co Ltd	Endonucleases; PA	New drug	1	CXHS2500089	2025.08.02
	Semaglutide(CSPC)	Cspc Ouyi Pharmaceutical Co Ltd; Cspc Baike (Shandong) Biopharmaceutical Co Ltd	GLP1R	New drug	2.2	CXHS2500090; CXHS2500091	2025.08.05
Therapeutic Biologicals	Onasemnogene abeparvovec	Novartis Pharma Schweiz Ag; Novartis Gene Therapies Inc; Beijing Novartis Pharma Co Ltd	SMN	Import	2.1	JXSS2500106	2025.08.02
	Human tetanus immunoglobulin	Guangdong Danxia Biological Pharmaceutical Co Ltd	Not applicable	New drug	3.4	CXSS2500078	2025.08.06

Data source: Pharmacodia Global

2.2.2 Special Designations

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	Rovadicitinib	Chiatai Tianqing	JAK2; ROCK2; ROCK1; TYK2	Chronic graft-versus-host disease (cGVHD)	NDA	NMPA-Break Through Therapy	2025.08.07
Biologicals	Trastuzumab rezetecan	Hengrui	HER2; TOP1	Pd-l1-positive (CPS≥1) locally recurrent unresectable or	Approved	NMPA-proposed Break Through	2025.08.08

				metastatic triple-negative breast cancer		Therapy	
	HB-0034	Huaota	IL-36R	Adult-onset generalized pustular psoriasis (GPP)	Phase III	NMPA-proposed Priority Review	2025.08.08
	Adebrelimab	Hengrui	PD-L1	Pd-l1-positive (CPS≥1) locally recurrent unresectable or metastatic triple-negative breast cancer	Approved	NMPA-proposed Break Through Therapy	2025.08.08
Cell Therapy	PA3-17	Persongen	CD7	Adult relapsed/refractory T-lymphoblastic leukemia/lymphoma	Phase I	NMPA-proposed Priority Review	2025.08.07

Data source：Pharmacodia Global

2.3 Global Novel Drug R&D Status in China

Drug Type	Drug Name	Company	Target	Indication	Highest Status	Latest Progress	Date
Chemicals	LY-03021	Luye	NE; DAT; GABAAR	Depression	Phase I	First patient enrolled in phase I trial	2025.08.03
	HEC-007	Hec-research	Updating	Overweight or obese	Phase I	Initiated phase I trial	2025.08.04
	Chiglitazar Sodium	Chipscreen	PPARα; PPARγ; PPARδ	Metabolism-related steatohepatitis	Approved	Presented positive data of phase II trial	2025.08.07
Biologicals	MRG-004A	Lepu	TF	Advanced pancreatic cancer	Phase III	Initiated phase III trial	2025.08.01
	TQB-2825	Chiatai Tianqing	CD3; CD20	Cd20-positive hematological malignancies	Phase II	Initiated phase I trial	2025.08.04
	Trastuzumab rezetecan	Hengrui	HER2; TOP1	Pd-l1-positive locally recurrent unresectable or metastatic triple-negative breast	Approved	Initiated phase III trial	2025.08.05

cancer

Data source: Pharmacodia Global

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Pharmacodia Global Database

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