

2024 년 FDA, EMA 신약 승인 현황

국가신약개발사업단 R&D기획팀 진주연 연구원

Overview

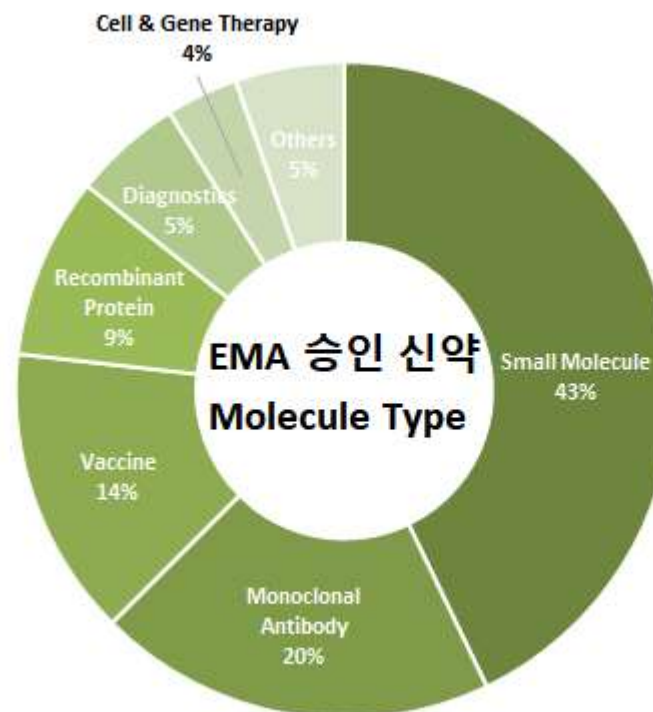
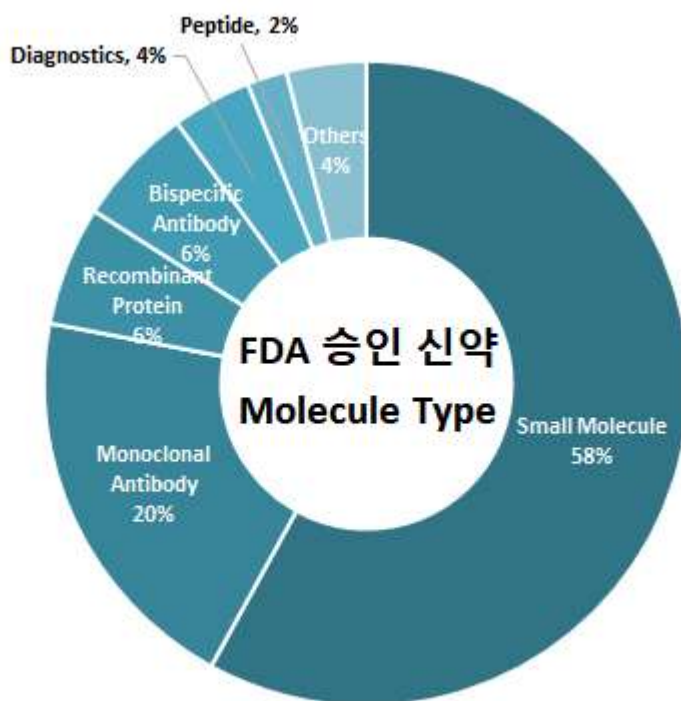
2024년 미국 식품의약국(FDA)과 유럽 의약품청(EMA)은 각각 50 건, 56 건의 신약을 승인하였다. 올해 두 기관에서 모두 승인을 획득한 신약은 8개(Exblifep, Voydeya, Piasky, Winrevair, Vyloy, Iqirvo, Hympavzi, Alhemo)이다.

FDA 승인 신약 50 건을 모달리티 별로 분류하였을 때, Small Molecule 이 29 건(58%)으로 가장 많았으며 mAb 가 10 건(20%), rProtein 과 BsAb 가 각각 3 건(각 6%), Diagnostics 가 2 건(4%), peptide 1 건(2%), Others*가 2 건(총 4%) 승인되었다. 질병 영역(TA)별로는 Oncology 가 14 건(28%), Immunology 가 7 건(14%), Metabolic Disorders 가 6 건(12%), Hematology 가 5 건(10%), Cardiovascular Diseases, Infectious Diseases, Neuroscience 가 각각 4 건(각 8%)가 등을 차지하였다.

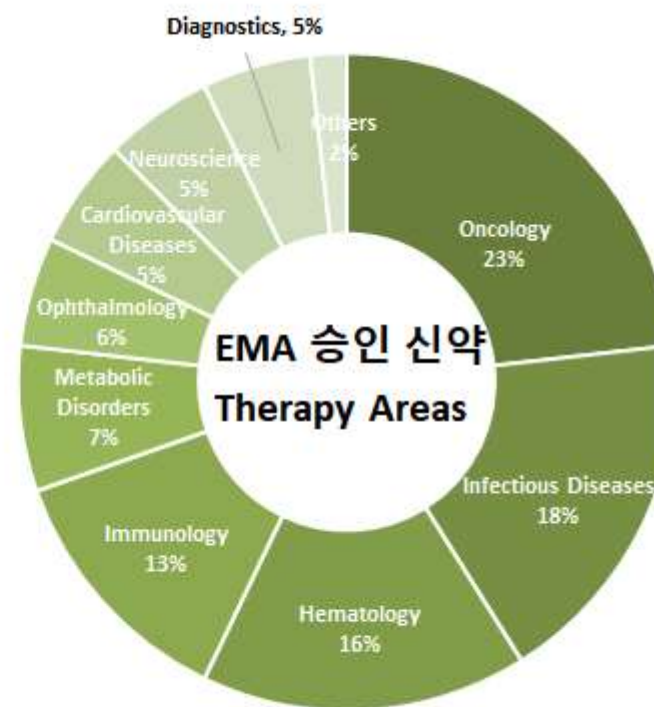
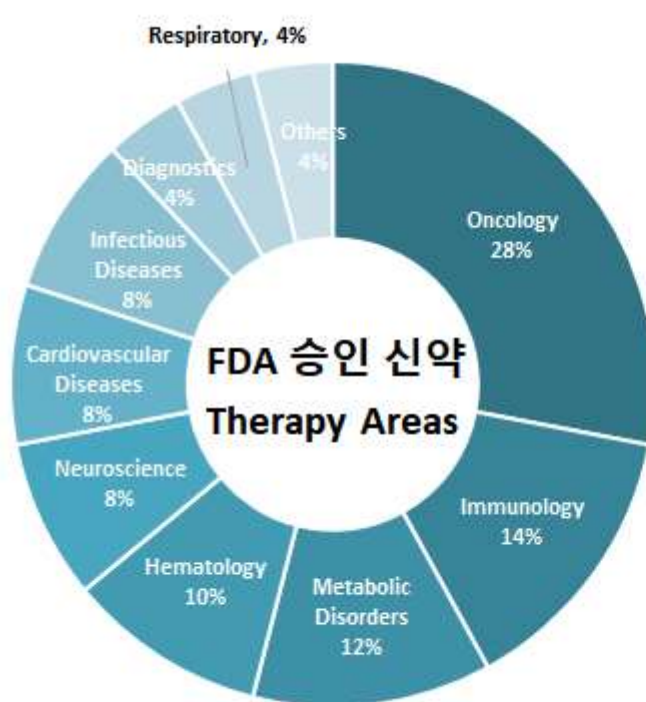
*Others: Antisense Oligonucleotide 1 건, Oligonucleotide 1 건

EMA 승인 신약 56 건의 경우, 모달리티 분포가 FDA 와 유사하게 Small Molecule 이 24 건(43%)으로 가장 많았으며, mAb 가 11 건(20%), Vaccine 이 8 건(14%), rProtein 이 5 건(9%), Diagnostics 가 3 건(5%), Cell & Gene Therapy 가 2 건(4%), Others**가 3 건(5%) 순으로 많았다. TA 별로는 Oncology 가 13 건(23%), Infectious Diseases 가 10 건(18%), Hematology 가 9 건(16%) Immunology 가 7 건(13%), Metabolic disorders 가 4 건(7%)순으로 많았으며, Cardiovascular Diseases, Diagnostics, Neuroscience, Ophthalmology 가 각각 3 건(각 5%)등 신약 승인을 받았다.

*Others: Antisense Oligonucleotide 1 건, Antibody Drug Conjugate 1 건, Synthetic Peptide 1 건



[2024 FDA vs EMA Modality]



[2024 FDA vs EMA Therapy Areas]

2024 FDA 승인 신약 리스트

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
1	Zelsuvmi	berdazimer	Ligand/Pelthos	Nitric oxide(NO)	Small molecule	Infectious Diseases	Molluscum contagiosum	01.05
2	Exblifep	Cefepime, Enmetazobactam	Allegra	Beta Lactamase	Small Molecule	Infectious Diseases	Complicated urinary tract infections	02.22
3	Letybo	letibotulinumtoxinA	Hugel	Botulinum neurotoxin type A(BoNT A)	Recombinant Protein	Others	Glabellar lines	02.29
4	Tevimbra	Tislelizumab	Beigene	PD1	Monoclonal Antibody	Oncology	Esophageal squamous cell carcinoma	03.13
5	Rezdiffra	Resmetirom	Madrigal	Thyroid hormone receptor-β	Small molecule	Metabolic Disorders	Noncirrhotic NASH with liver scarring	03.14
6	Tryvio	Aprocitentan	Idorsia	Endothelin receptor	Small Molecule	Cardiovascular Diseases	Hypertension	03.19
7	Duvyzat	Givinostat	Italfarmaco	Histone deacetylase	Small Molecule	Neuroscience	DMD	03.21
8	Winrevair	Sotatercept	Merck & Co	.Activin receptot type 2	Recombinant Protein	Cardiovascular Diseases	Pulmonary arterial hypertension	03.26
9	Vafseo	Vadadustat	Akebia	Hypoxia-inducible factor prolyl hydroxylase (HIF-PH)	Small Molecule	Hematology	Anaemia due to chronic kidney disease	03.27
10	Voydeya	Danicopan	AstraZeneca/Alexion	Complement factor D(CFD)	Small Molecule	Hematology	Extravascular haemolysis with paroxysmal nocturnal haemoglobinuria	03.29
11	Zevtera	Ceftobiprole medocaril sodium	Basilea Pharmaceutica	Penicillin binding proteins(PBP)	Small Molecule	infectious Diseases	Bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia	04.03

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
12	Lumisight	Pegulicianine	Lumicell	Cathepsin	Diagnostics(fluorescent)	Diagnostics	Imaging agent for cancerous tissue	04.17
13	Anktiva	Nogapendekin alfa inbakicept-pmIn	Immunitybio/Altor Bioscience	IL-15 receptor	Recombinant Protein	Oncology	Bladder cancer	04.22
14	Ojemda	Tovorafenib	Day One Biopharmaceuticals	RAF kinase	Small Molecule	Oncology	Paediatric low-grade glioma	04.23
15	Xolremdi	Mavorixafor	X4 Pharmaceuticals	CXC chemokine receptor 4	Small Molecule	Immunology	WHIM syndrome	04.26
16	Imdelltra	Tarlatamab	Amgen	DLL3 × CD3 T-cell	Bispecific Antibody	Oncology	Small-cell lung cancer (SCLC)	05.16
17	Iqirvo	Elafibranor	Ipsen	PPAR α , δ	Small Molecule	Immunology	PBC	06.01
18	Piasky	Crovalimab	Genentech/Chugai	Complement 5(C5)	Monoclonal Antibody	Hematology	Paroxysmal nocturnal hemoglobinuria	06.02
19	Rytelo	Imetelstat	Geron	Telomerase	Oligonucleotide	Oncology	Myelodysplastic syndromes	06.06
20	Sofdra	Sofpironium	Botanix	Muscarinic acetylcholine receptor 3(M3)	Small Molecule	Others	Primary axillary hyperhidrosis	06.18
21	Ohtuvayre	Ensifentrine	Verona	PDE3, 4	Small Molecule	Respiratory	Chronic obstructive pulmonary disease(COPD)	06.26
22	Kisunla	Donanemab	Eli Lilly	Amyloid β	Monoclonal Antibody	Neuroscience	Alzheimer disease	07.02
23	Leqselvi	Deuruxolitinib	Sun Pharma	JAK kinase 1, 2	Small Molecule	Immunology	Alopecia areata	07.25
24	Voranigo	Vorasidenib	Servier	IDH1, 2	Small Molecule	Oncology	Astrocytoma or oligodendroglioma	08.06
25	Yorvipath	Palopegteriparatide	Ascendis	Parathyroid hormone	Peptide	Metabolic Disorders	Hypoparathyroidism	08.09
26	Nemluvio	Nemolizumab-ilto	Galderma	IL-31A	Monoclonal Antibody	Immunology	Prurigo nodularis	08.12

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
27	Livdelzi	Seladelpar	Gilead	PPARδ	Small Molecule	Immunology	PBC	08.14
28	Niktimvo	Axatilima	Incyte/Syndax	CSF-1R	Monoclonal Antibody	Immunology	GvHD	08.14
29	Lazcluze	Lazertinib	Janssen/J&J	EGFR	Small Molecule	Oncology	NSCLC	08.19
30	Miplyffa	Arimoclomol	Zevra Denmark	Hsp70	Small Molecule	Metabolic Disorders	Niemann-Pick disease type C	09.02
31	Ebglyss	Iebrikizumab	Eli Lilly	IL-13	Monoclonal Antibody	Immunology	Atopic dermatitis	09.13
32	Aqneursa	Ievacetylleucine	Intrabio	MOA unknown	Small Molecule	Neuroscience	Niemann-Pick disease type C	09.24
33	Cobenfy	Xanomeline and trospium chloride	Bristol Myers Squibb/Karuna	M1/M4 muscarinic receptor, pan-muscarinic receptor	Small Molecule	Neuroscience	Schizophrenia	09.26
34	Flyrcado	Flurpiridaz F 18	GE Healthcare	Mitochondrial complex I	Diagnostics(Radioactive)	Cardiovascular Diseases	Myocardial ischaemia and infarction imaging	09.27
35	Itovebi	Inavalisib	Genentech	PI3Kα	Small Molecule	Oncology	Breast cancer	10.01
36	Hympavzi	Marstacimab	Pfizer	TFPI	Monoclonal Antibody	Hematology	Hemophilia A;Hemophilia B	10.11
37	Vyloy	zolbetuximab	Astellas	Claudin-18.2	Monoclonal Antibody	Oncology	Gastric or GEJ adenocarcinoma	10.18
38	Orlynvah	Sulopenem etzadroxil, probenecid	Iterum Therapeutics	Penem antibacterial and a renal tubular transport inhibitor	Small Molecule	Infectious Diseases	Uncomplicated urinary tract infections	10.25
39	Ziihera	Zanidatamab-hrii	Jazz/Zymeworks	HER2 × HER2	Bispecific Antibody	Oncology	HER2-positive biliary tract cancer	11.02
40	Revuforj	Revumenib	Syndax	Menin	Small Molecule	Oncology	Acute leukaemia	11.15
41	Attruby	Acoramidis	Bridgebio Pharma	Transthyretin	Small Molecule	Metabolic Disorders	ATTR-CM	11.22

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
42	Rapiblyk	Landiolol	AOP Orphan Pharmaceuticals	Beta adrenergic receptor	Small Molecule	Cardiovascular Diseases	Supraventricular tachycardia	11.22
43	Iomervu	Iomeprol	Bracco Diagnostics	Diagnostic contrast agent	Small Molecule	Diagnostics	Intra-arterial and intravenous imaging	11.27
44	Alhemo	Concizumab	Novo Nordisk	TFPI	Monoclonal Antibody	Hematology	Hemophilia A; Hemophilia B	12.02
45	Alyftrek	Vanzacaftor, Tezacaftor, Deutivacaftor	Vertex	CFTR	Small Molecule	Respiratory	Cystic fibrosis	12.02
46	Bizengri	Zenocutuzumab	Merus	HER2 × HER3	Bispecific Antibody	Oncology	NSCLC and pancreatic adenocarcinoma	12.04
47	Crenessity	Crinecerfont	Neurocrine	CRF type 1 receptor	Small Molecule	Metabolic Disorders	Classic congenital adrenal hyperplasia	12.13
48	Unloxyt	Cosibelimab	Checkpoint	PDL1	Monoclonal Antibody	Oncology	Cutaneous squamous cell carcinoma	12.13
49	Ensacove	Ensartinib	Xcovery	ALK	Small Molecule	Oncology	ALK-positive NSCLC	12.18
50	Tryngolza	Olezarsen	Olezarsen	APOC-III	Antisense Oligonucleotide	Metabolic Disorders	Familial chylomicronemia syndrome	12.19

2024 EMA 승인 신약 리스트

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
1	Rystiggo	Rozanolixizumab	UCB Pharma	IgG Receptor FcRn Large Subunit p51	Monoclonal Antibody	Immunology	Myasthenia Gravis	01.05
2	Spexotras	Trametinib dimethyl sulfoxide	Novartis Europharm Limited	Dual Specificity Mitogen-Activated Protein Kinase Kinase 1(MAP2K1)	Small Molecule	Oncology	Glioma	01.05
3	Krazati	Adagrasib	Bristol-Myers Squibb Pharma EEIG	GTPase Kras	Small Molecule	Oncology	Carcinoma, Non-Small-Cell Lung	01.05
4	Omjjara	Momelotinib dihydrochloride monohydrate	GlaxoSmithKline Trading Services Limited	JAK1, JAK2, ACVR1	Small Molecule	Oncology	Splenomegaly;Myeloproliferative Disorders	01.25
5	Skyclarys	Omaveloxolone	Biogen Netherlands B.V	.Kelch Like ECH Associated Protein 1	Small Molecule	Neuroscience	Friedreich Ataxia	02.09
6	Casgevy	Exagamglogene autotemcel	Vertex Pharmaceuticals (Ireland) Limited	BCL11A gene	Gene-Modified Cell Therapy	Hematology	Beta-Thalassemia;Anemia, Sickle Cell	02.09
7	Velsipity	Etrasimod arginine	Pfizer Europe MA EEIG	Sphingosine 1-Phosphate Receptor	Small Molecule	Immunology	Colitis, Ulcerative	02.16
8	Ryzneuta	Efbemalenograstim alfa	Evive Biotechnology Ireland Limited	Granulocyte Colony Stimulating Factor Receptor(G-CSFR)	Recombinant Protein	Oncology	Chemotherapy Induced Neutropenia	03.21

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
9	Exblifep	Cefepime, Enmetazobactam	ADVANZ PHARMA Limited	Beta Lactamase	Small Molecule	Infectious Diseases	Urinary Tract Infections	03.21
10	Filspari	Sparsentan	Vifor France	Endothelin 1 Receptor, Type 1 Angiotensin II Receptor	Small Molecule	Immunology	IgA Glomerulonephritis	04.19
11	Voydeya	Danicopan	Alexion Europe SAS	Complement factor D(CFD)	Small Molecule	Hematology	Paroxysmal Nocturnal Hemoglobinuria	04.19
12	Incellipan	Influenza virus A	Seqirus Netherlands B.V	.Immune Response	Vaccine	Infectious Diseases	Human Influenza	04.19
13	Celldemic	Influenza virus A	Seqirus Netherlands B.V	.Immune Response	Vaccine	Infectious Diseases	Human Influenza	04.19
14	Zynyz	Retifanlimab	Incyte Biosciences Distribution B.V	.Programmed Cell Death Protein 1(PD-1)	Monoclonal Antibody	Oncology	Merkel Cell Carcinoma	04.19
15	Emblaveo	Avibactam, Aztreonam	Pfizer Europe MA EEIG	Beta Lactamase	Small Molecule	Infectious Diseases	Urinary Tract Infections	04.22
16	Fabhalta	Iptacopan hydrochloride	Novartis Europharm Limited	Complement Factor B(CFB)	Small Molecule	Hematology	Paroxysmal Hemoglobinuria	05.17
17	Awikli	Insulin icodec	Novo Nordisk A/S	Insulin Receptor	Recombinant Protein	Metabolic Disorders	Diabetes Mellitus	05.17
18	Lytenava	Bevacizumab	Outlook Therapeutics Ltd.	Vascular Endothelial Growth Factor A	Monoclonal Antibody	Ophthalmology	Wet Macular Degeneration	05.27

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
19	Neotricon	Dopamine hydrochloride	BrePco Biopharma Limited	adrenergic receptors	Small Molecule	Cardiovascular Diseases	Hypotension	05.27
20	Agilus	Dantrolene sodium	Norgine B.V	.Ryanodine Receptor 1	Small Molecule	Metabolic Disorders	Malignant Hyperthermia	05.29
21	Qalsody	Tofersen	Biogen Netherlands B.V.	Superoxide Dismutase 1(SOD 1)	Antisense Oligonucleotide	Neuroscience	Amyotrophic Lateral Sclerosis(ALS)	05.29
22	Fluenz	Influenza virus A	AstraZeneca AB	Immune Response	Vaccine	Infectious Diseases	Human Influenza	03.06
23	Altuvoct	Efanesoctocog alfa	Swedish Orphan Biovitrum AB (publ)	Coagulation Factor VIII	Recombinant Protein	Hematology	Hemophilia A	06.17
24	Truqap	Capivasertib	AstraZeneca AB	Serine/threonine kinase (AKT) 1, 2, 3	Small Molecule	Oncology	Breast Neoplasms	06.17
25	Fruzaqla	Fruquintinib	Takeda Pharmaceuticals International AG Ireland	Vascular Endothelial Growth Factor Receptor	Small Molecule	Oncology	Colorectal Neoplasms	06.20
26	Obgemsa	Vibegron	Pierre Fabre Medicament	Beta 3 Adrenergic Receptor	Small Molecule	Others	Urinary Bladder	06.27
27	Ixchiq	Chikungunya virus	Valneva Austria GmbH	Immune Response	Vaccine	Infectious Diseases	Chikungunya Fever	06.28
28	Cejemly	Sugemalimab	SFL Pharmaceuticals Deutschland	Programmed Cell Death Protein 1(PD-1)	Monoclonal Antibody	Oncology	Carcinoma, Non-Small-Cell Lung	07.24

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
29	Zegalogue	Dasiglucagon hydrochloride	Zealand Pharma A/S	Glucagon Receptor	Synthetic Peptide	Metabolic Disorders	Diabetes Mellitus	07.24
30	Beqvez (previously Durveqtix)	Fidanacogene elaparvovec	Pfizer Europe MA EEIG	Coagulation Factor IX	Gene Therapy	Hematology	Hemophilia B	07.24
31	GalliaPharm	Gallium (68Ga) chloride;germanium (68Ge) chloride	Eckert & Ziegler Radiopharma GmbH	n/d	Diagnostics(Radioactive)	Diagnostics	Radionuclide Imaging	01.08
32	Adzynma	Aapadamtase alfa;cinaxadamtase alfa	Takeda Manufacturing Austria AG	A Disintegrin And Metalloproteinase With Thrombospondin Motifs 13(ADAMTS 13)	Recombinant Protein	Hematology	Purpura, Thrombotic Thrombocytopenic	01.08
33	Balversa	Erdafitinib	Janssen-Cilag International N.V	.Fibroblast Growth Factor Receptor 3	Small Molecule	Oncology	Urologic Neoplasms	08.22
34	Piasky	Crovalimab	Roche Registration GmbH	Complement 5(C5)	Monoclonal Antibody	Hematology	Paroxysmal Hemoglobinuria	08.22
35	Eurneffy	Epinephrine	Ars Pharmaceuticals Irl Limited	Adrenergic Receptor	Small Molecule	Immunology	Anaphylaxis	08.22
36	Tauvid	Flortaucipir (18F)	Eli Lilly Nederland B.V	.Tau protein	Diagnostics(Radioactive)	Diagnostics	Radionuclide Imaging	08.22

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
37	Akantior	Polihexanide	SIFI SPA	Cell Membrane	Small Molecule	Ophthalmology	Acanthamoeba Keratitis	08.22
38	Ordspono	Odronextamab	Regeneron Ireland Designated Activity Company (DAC)	B Lymphocyte Antigen CD20; CD3	Monoclonal Antibody	Oncology	Lymphoma, Follicular	08.22
39	Steqeyma	Ustekinumab	Celltrion Healthcare Hungary Kft	.IL-12 Subunit Beta, IL-23 Subunit Alpha	Monoclonal Antibody	Immunology	Psoriasis	08.22
40	Winrevair	Sotatercept	Merck Sharp & Dohme B.V	.Activin receptot type 2	Recombinant Protein	Cardiovascular Diseases	Pulmonary Hypertension	08.22
41	mResvia	Respiratory syncytial virus	Moderna Biotech Spain, S.L	.Immune Response	Vaccine	Infectious Diseases	Respiratory Syncytial Virus Infections	08.22
42	Vevizye	Ciclosporin	Laboratoires Théa	Calcineurin	Small Molecule	Ophthalmology	Keratoconjunctivitis Sicca	09.19
43	Loqtorzi	Toripalimab	TMC Pharma (EU) Limited	Programmed Cell Death Protein 1(PD- 1)	Monoclonal Antibody	Oncology	Esophageal Squamous Cell Carcinoma	09.19
44	Anzupgo	Delgocitinib	LEO Pharma A/S	Janus family kinases(JAKs)	Small Molecule	Immunology	Atopic Dermatitis	09.19
45	Vyloy	Zolbetuximab	Astellas Pharma Europe B.V	.Claudin-18.2	Monoclonal Antibody	Oncology	Stomach Neoplasms, Esophageal Neoplasms	09.19
46	Kayfanda	Odevixibat sesquihydrate	Ipsen Pharma	ileal bile acid transporter(IBAT)	Small Molecule	Metabolic Disorders	Pruritus, Alagille Syndrome	09.19

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
47	Iqirvo	Elafibranor	Ipsen Pharma	PPAR α , δ	Small Molecule	Immunology	Biliary cirrhosis	09.19
48	Yuvanci	Macitentan, tadalafil	Janssen-Cilag International V	Endothelin Receptor	Small Molecule	Cardiovascular Diseases	Pulmonary Hypertension	09.27
49	Penbraya	Meningococcal polysaccharides (A, B, C, W, Y) and recombinant fHbp protein	Pfizer Europe MA EEIG	Meningococcal Capsular Polysaccharide Antigen	Vaccine	Infectious Diseases	Meningitis, Meningococcal	11.14
50	Elahere	Mirvetuximab soravtansine	AbbVie Deutschland GmbH & Co. KG	Folate Receptor α	Antibody Drug Conjugate	Oncology	Ovarian Neoplasms;Fallopian Tube Neoplasms;Peritoneal Neoplasms	11.14
51	Fluad	A/(H1N1)-like virus antigen,A/(H3N2)-like virus antigen,B (Victoria lineage)-like virus antigen	Seqirus Netherlands B.V	.Hemagglutinin	Vaccine	Infectious Diseases	Influenza, Human	11.15
52	Flucelvax	A/(H1N1)-like virus antigen,A/(H3N2)-like virus antigen,B (Victoria lineage)-like virus antigen	Seqirus Netherlands B.V	.Hemagglutinin	Vaccine	Infectious Diseases	Influenza, Human	11.15
53	Hympavzi	Marstacimab	Pfizer Europe MA EEIG	TFPI	Monoclonal Antibody	Hematology	Hemophilia A;Hemophilia B	11.18

No	Drug name	Active substance	Company	Target	Molecule Type	Therapy Areas	Indication	Approval date
54	Theralugand	lutetium (177Lu) chloride	Eckert & Ziegler Radiopharma GmbH	Carrier molecule-dependent	Diagnostics(Radioactive)	Diagnostics	Radionuclide Imaging	11.22
55	Alhemo	Concizumab	Novo Nordisk A/S	TFPI	Monoclonal Antibody	Hematology	Hemophilia A; Hemophilia B	12.13
56	Buprenorphine Neuraxpharm	Buprenorphine hydrochloride	Neuraxpharm Pharmaceuticals S.L	.Mu Type Opioid Receptor	Small Molecule	Neuroscience	Opioid-Related Disorders	12.19

<문의>

국가신약개발사업단 R&D기획팀 진주연 연구원(jyjin@kddf.org)

Reference

<https://www.nature.com/articles/d41573-025-00001-5>

https://www.ema.europa.eu/en/documents/report/human-medicines-2024_en.pdf

<https://pharma.globaldata.com/>

<https://www.cortellis.com/intelligence/home.do>