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FDA Drug Approvals 2024: A Comprehensive Review

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Abstract

The year 2024 has been pivotal for the pharmaceutical industry, with the U.S. Food and Drug Administration (FDA) granting approval to a diverse array of new drugs. These approvals highlight significant strides in therapeutic innovation, targeting a spectrum of diseases from rare genetic disorders to prevalent chronic conditions. This article provides a detailed examination of the FDA-approved drugs of 2024, focusing on their therapeutic indications, mechanisms of action, clinical trial evidence, side effects, and storage conditions. Notable approvals include groundbreaking treatments in cardiovascular health, infectious diseases, neurology, and oncology, each offering novel therapeutic options and potential improvements in patient outcomes. About 41 drugs have been approved by USFDA till June 2024. This comprehensive review aims to inform healthcare professionals and researchers of the latest advancements, fostering a deeper understanding of emerging trends in drug development and their implications for future medical practice.

Keywords: FDA approval, pharmaceutical innovations, USFDA approved drugs 2024, clinical trials, drug development

INTRODUCTION

The landscape of pharmaceutical innovation continues to evolve rapidly, with 2024 marking a significant year for the approval of new drugs by the U.S. Food and Drug Administration (FDA). These approvals represent critical advancements in the treatment of a variety of conditions, ranging from rare genetic disorders to widespread chronic diseases. The introduction of these new medications not only underscores the ongoing commitment to addressing unmet medical needs but also highlights the progress in research and development within the pharmaceutical industry [1].

In 2024, the FDA has approved several noteworthy drugs, each bringing unique mechanisms of action, improved efficacy, and enhanced safety profiles. These medications have been developed to target specific pathways and disease mechanisms, offering patients novel therapeutic options that were previously unavailable. The approvals span a wide range of therapeutic areas, including cardiovascular diseases, infectious diseases, neurological conditions, and oncology [2].

This article aims to provide a comprehensive overview of the FDA-approved drugs in 2024, detailing their indications, mechanisms of action, and potential impact on patient care. By examining these new treatments, healthcare professionals and researchers can gain valuable insights into the latest trends and advancements in drug development, ultimately contributing to improved patient outcomes and advancing the field of medicine (Table 1) (Figure 1).

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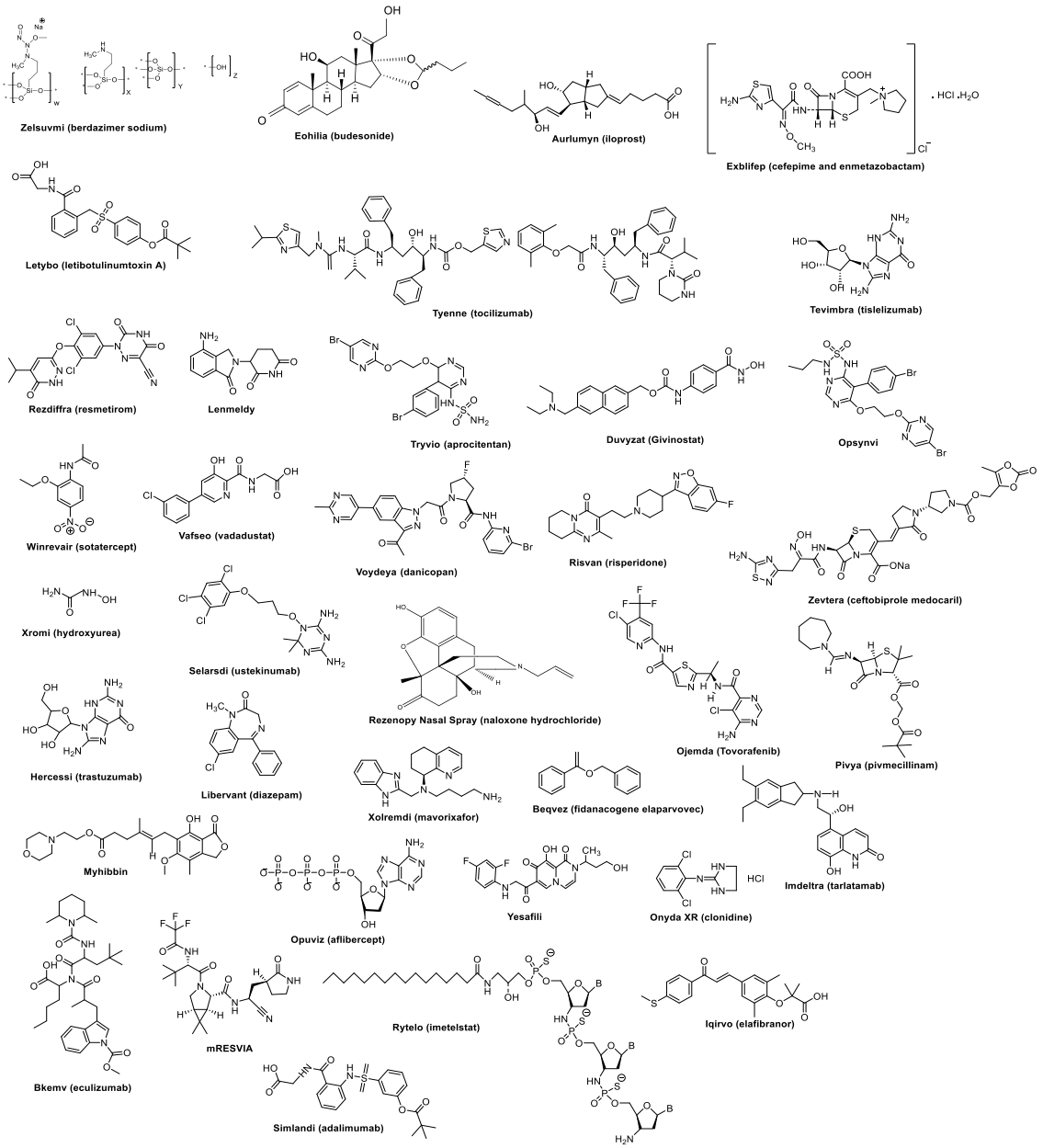

Figure 1. Structures of FDA-approved 2024 drugs.

Zelsuvmi (berdazimer sodium)

Zelsuvmi (1), also named Berdazimer sodium, was discovered and developed by Ligand Pharmaceuticals Incorporated on January 5, 2024 [1]. The topical medication Zelsuvmi is primarily used to treat Molluscum contagiosum (MC), a viral skin disease [2]. Zelsuvmi's active ingredient is berdazimer, a nitric oxide (NO)-releasing substance having broad-spectrum antibacterial and antiviral properties [3]. It's unclear exactly how it heals Molluscum contagiosum, but it's believed to be connected to NO's antiviral and antibacterial qualities [2]. Zelsuvmi comes in two tubes, one containing berdazimer gel and the other a hydrogel. These gels must be thoroughly mixed before being applied. After that, the mixed gel is applied to each lesion once a day for a maximum of 12 weeks. It's important to let the gel dry for around ten minutes and to wait an hour after application before washing the treated area [3]. Common adverse effects include skin reactions at the application site, including redness, swelling, itching, and irritation. Zelsuvmi should not be used near the mouth, eyes, or genitalia; it should only be applied externally. Zelsuvmi should be refrigerated prior to administration. It must be

disptemperature and room temperature and discarded sixty days after being taken out of the refrigerator. Pharmacokinetic studies indicate that berdazimer exposure to the system is restricted when applied topically. However, studies on animal toxicity do identify some risks at high doses; however, these are not instantly transferable to topical treatment in people [4].

Eohilia (budesonide)

Eohilia (2), also named Budesonide, was discovered and developed by Takeda Pharmaceutical Company Limited on February 9, 2024. It is used to treat eosinophilic esophagitis (EoE) to lessen esophageal inflammation and enhance swallowing capacity [5]. Budesonide is a corticosteroid with an anti-inflammatory action that is present in the eohilia [6]. Respiratory tract infections, fungal infections of the mouth, throat, and esophagus, headaches, stomach and intestinal infections, throat irritation, adrenal suppression, and acid-related damage to the esophageal lining – which affected at least 2% of patients – are among the common side effects of eohilia [7]. The lining of the esophagus may sustain damage from eohilia due to acidity. Chest pain, dysphagia, or heartburn are warning signs or symptoms. Stored at 36° to 77°F; avoid freezing [8].

Aurlumyn (iloprost)

Aurlumyn (3), also known as iloprost, was discovered and developed by Eicos Sciences Inc. on February 14, 2024. Adults with severe frostbite may benefit from the use of Aurlumyn, a prostacyclin mimetic (synthetic analog of prostacyclin PGI2) administered intravenously (into a vein) to lower their risk of digit amputations (the surgical removal of fingers and toes) [9]. Aurlumyn (iloprost) functions as a vasodilator, relaxing the muscles in artery walls by binding with similar affinity to human prostacyclin (Prostanoid IP) and prostaglandin EP1 receptors [10]. It shows hypotension, a condition characterized by low blood pressure, can lead to symptoms, such as disorientation, blurred vision, or dizziness, particularly when standing. It is given intravenously as an infusion. Headache, flushing, palpitations, tachycardia, rapid heartbeat, nausea, vomiting, vertigo, and hypotension (low blood pressure) are among the most frequent adverse effects. Store in unopened vials at 20°C to 25°C [11].

Amtagvi (lifileucel)

Amtagvi (4), also known as lifileucel, was discovered and developed by Iovance Biotherapeutics, Inc. on February 16, 2024. Adult patients with unresectable or metastatic melanoma are treated with it as cellular therapy, especially if their malignancy has not responded to prior therapies, like PD-1-blocking antibodies and, if necessary, BRAF inhibitors with or without MEK inhibitors [12]. Amtagvi is an immunotherapy using autologous T cells. Fighting cancer entails removing T cells from a patient's tumor, growing and altering them in a laboratory, and then reintroducing the cells into the patient (FDA) (AMTAGVI) [13]. To prepare the patient's body for the therapy, a chemotherapy regimen that depletes lymph nodes is usually followed. Patients may receive interleukin-2 (IL-2) to boost T-cell expansion following the injection of Amtagvi [14]. Chills, fever, exhaustion, tachycardia, diarrhea, and low blood cell counts are typical side effects that can raise the risk of infection. Close observation is necessary due to the possibility of serious side effects, including organ impairment, persistent cytopenia, and severe infections [15].

Exblifep (cefepime and enmetazobactam)

Exblifep (5) was discovered and developed by Allecra Therapeutics on February 22, 2024. In Exblifep, enmetazobactam, a beta-lactamase inhibitor, and cefepime (Maxipime), a fourth-generation cephalosporin, are combined [16]. When the bacterium causing a complex urinary tract infection (cUTI) is resistant to other antibiotics, particularly if the resistance is brought on by extended-spectrum beta-lactamases (ESBLs), this medication is used. Additionally, it is used for kidney infections (pyelonephritis) brought on by certain bacteria that are susceptible to Exblifep, including *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, and the *Enterobacter cloacae* complex [17]. Exblifep side effects include headaches, elevated liver enzyme transaminases, high bilirubin levels, and infusion side effects, such as vein irritation (phlebitis). At least 5% of patients

experienced these side effects. Patients who have experienced severe hypersensitivity responses to cefepime, enmetazobactam, or other beta-lactam antibiotic medications should not use exblifep [18].

Simlandi (adalimumab-ryvk)

Simlandi (6), also known as adalimumab, was discovered and developed by Alvotech and Teva Pharmaceutical Industries Ltd. on February 23, 2024. The TNF-alpha inhibitor Simlandi is a biosimilar to Humira that can be used interchangeably [19]. Plaque psoriasis, Crohn's disease, ulcerative colitis, rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, and uveitis are among the autoimmune disorders for which it is used to lessen pain, inflammation, and skin symptoms [20]. Headache, cold symptoms (stuffy nose, sinus pain, sneezing, sore throat), rash or redness, bruising, itching, or swelling where the injection was administered are common side effects of Simlandi [21]. Age, severity, and the ailment being treated all effect how much and how often Simlandi is administered. The Simlandi single dose autoinjector, 40 mg/0.4 mL, is available. Store this medication refrigerated between 36°F and 46°F (2°C and 8°C) in its original carton [22].

Letybo (letibotulinumtoxinA-wlbg)

Letybo (7), also known as letibotulinumtoxin A, was discovered and developed by Hugel, Inc. on February 29, 2024. It is a neurotoxin that acts by preventing the release of acetylcholine, a nerve transmitter that causes muscles to contract, from reaching the muscles [23]. The delayed breakdown of letibotulinumtoxin A and the development of axonal sprouts, which counteract the effects of letybo over several months, cause a gradual recovery of muscular function. Adults with moderate to severe brow furrows (glabellar lines) can temporarily enhance their look by injecting Letybo into their muscles. Corrugator and/or procerus muscle activity is linked to these frown lines [24]. It might have detrimental side effects that are potentially fatal, such as difficulties speaking, breathing, or swallowing. Store unopened Letybo vials in a refrigerator between 2°C to 8°C (36°F to 46°F) in the original carton to protect them from light [25].

Jubbonti (denosumab-bbdz)

Jubbonti (8), also known as denosumab, was discovered and developed by Sandoz Inc. on March 5, 2024. Jubbonti, a monoclonal antibody that targets and inhibits RANK ligand (RANKL), is a biosimilar that can be used interchangeably with Prolia (denosumab) [26]. Subcutaneous injections of Jubbonti are used to treat osteoporosis in postmenopausal women and to promote bone mass. Life-threatening hypersensitivity responses, osteonecrosis, severe hypocalcemia, dyspnea, serious issues with the jaw and thigh bones, and fractures of the bones are common adverse effects [27].

Wyost (Denosumab-bbdz)

Wyost (9) was discovered and developed by Sandoz Inc. Wyost is an oral medicine that is a member of the sphingosine 1-phosphate (S1P) receptor modulator pharmacological class [28]. To lessen the frequency of relapses and slow the advancement of physical disability, it is mostly used to treat relapsing types of multiple sclerosis (MS). To lessen inflammation and autoimmune attacks on the brain system, wyost binds to S1P receptors and blocks certain lymphocytes—a subset of white blood cells – from leaving lymph nodes and entering the central nervous system [29]. Headache, increased liver enzymes, and infections, like upper respiratory tract infections, are typical adverse effects. Macular edema, liver damage, and bradycardia are examples of serious side effects. Wyost should be kept between 68°F and 77°F (20°C and 25°C) at room temperature [30].

Tyenne (Tocilizumab-aazg)

Tyenne (10), discovered and developed by Fresenius Kabi on March 5, 2024, works by targeting and binding to interleukin-6 (IL-6), a protein associated with inflammation [31]. Tyenne blocks IL-6 receptor-mediated signaling via both membrane-bound and soluble forms. This proinflammatory cytokine is produced locally by synovial and endothelial cells in joints, as well as by a variety of immune system cells, such as T- and B-cells, lymphocytes, monocytes, and fibroblasts. It is known to exacerbate

inflammatory disorders, such as rheumatoid arthritis [32]. Actemra (tocilizumab) and Tyenne are biosimilars that can be administered subcutaneously or intravenously. Serious and potentially fatal hypersensitivity responses, stomach or intestinal perforations, hepatotoxicity, upper respiratory tract infections (including the common cold and sinus infections), headaches, and elevated blood pressure (hypertension) are among the frequent side effects. Refrigerating Tyenne at 36°F to 46°F (2°C to 8°C) is recommended [33].

Tevimbra (tislelizumab-jsgr)

Tevimbra (11), was discovered and developed by BeiGene, Ltd. on March 13, 2024. Tevimbra is highly specific for PD-1. Tevimbra is an intravenous (IV) antibody that blocks the programmed death receptor-1 (PD-1) and is used to treat individuals with metastatic esophageal squamous cell carcinoma [34]. Tevimbra can result in severe, potentially fatal immune system reactions as well as other side effects, such as flushing, lightheadedness, itching, or rash. kept in the original container and refrigerated between 2°C and 8°C (36°F and 46°F) to prevent light deterioration [35].

Rezdiffra (resmetirom)

Rezdiffra (12) was discovered and developed by Madrigal Pharmaceuticals, Inc. on March 14, 2024, and was the first drug to be approved for NASH. NASH is often referred to as metabolic dysfunction-associated steatohepatitis (MASH) or nonalcoholic fatty liver disease. Rezdiffra functions by partially agonistically stimulating thyroid hormone receptor-beta (THR-beta), the primary thyroid hormone receptor in the liver, hence decreasing hepatic triglyceride levels [36]. NASH and its symptoms, including liver fibrosis, cirrhosis, and edema, are linked to high lipid levels in the liver. Serious adverse effects from rezdiffra include vomiting, diarrhea, itching, and liver damage. Gallstones and other gallbladder issues are also possible. kept in storage at ambient temperature (68°F to 77°F; 20°C to 25°C) [37].

Lenmeldy (atidarsagene autotemcel)

Lenmeldy (13) was discovered and developed by Orchard Therapeutics on March 18, 2024. Lenmeldy uses the patient's own customized stem cells to assist the body in producing the ARSA enzyme, which helps halt the course of MLD [38]. Children with some forms of metachromatic leukodystrophy can be treated with a gene therapy called Lenmeldy. Children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early symptomatic early juvenile metachromatic leukodystrophy (MLD) should be treated with lentenmeldy [39]. Fever with a low neutrophil count, oral inflammation, respiratory tract infections, rash, infections connected to the device, other viral infections, fever, gastroenteritis, and an enlarged liver were the most frequent side effects [40].

Tryvio (Aprocitentan)

Tryvio (14), discovered and developed by Idorsia Ltd., was FDA-approved on March 19, 2024, and is the first oral antihypertensive therapy with a new mechanism of action to be approved in almost 40 years. Tryvio functions by blocking endothelin (ET)-1 from binding to ETA and ETB [41]. The amino acid peptide endothelin-1 is produced by a variety of tissues and cells, including the renal medulla, macrophages, endothelium, and vascular smooth muscle cells. Vasoconstriction (the narrowing of blood vessels), fibrosis (the thickening and scarring of tissue), and inflammation are among the outcomes linked to it [42]. Tryvio reduces blood pressure by blocking the binding of ET-1 [43]. Tryvio carries a boxed warning for embryo-fetal damage due to its potential to result in severe birth abnormalities, lower sperm and hemoglobin levels, liver toxicity, edema, and fluid retention. Tryvio pills should be kept between 68°F and 77°F (20°C and 25°C) at room temperature [44].

Duvyzat (Givinostat)

Duvyzat (15), discovered and developed by Italfarmaco Group, got FDA approval on March 21, 2024, based on positive results from the EPIDYS clinical trial (NCT02851797). According to this experiment,

patients on Duvyzat took longer than those taking a placebo to complete the four-stair climb assessment, which was both statistically significant and clinically important. To slow down the symptoms and progression of Duchenne muscular dystrophy (DMD), Duvyzat is used as a treatment [45]. Duvyzat functions by blocking HDAC enzymes, which are implicated in the deterioration of muscle. Duvyzat slows down muscle degradation in this muscle-wasting disease, DMD, by blocking HDAC. Dystrophin insufficiency in DMD leads to overactivity of the enzyme histone deacetylases (HDACs), which causes muscle difficulties and DMD symptoms [46]. Diarrhea, nausea, vomiting, fever, stomach pain, thrombocytopenia, and elevated blood fat levels are among the most frequent adverse effects. Duvyzat is an oral suspension administered orally twice a day with meals. stored between 68°F and 77°F (20°C to 25°C) [47].

Opsynvi (Macitentan and Tadalafil)

Opsynvi (16), discovered and developed by Actelion Pharmaceuticals US, Inc., got FDA approval on March 22, 2024. For adults with pulmonary arterial hypertension (PAH, WHO Group I) of WHO functional class (FC) II–III, oppenvi (macitentan, an endothelin receptor antagonist (ERA), and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor) is an oral, once-daily tablet that reduces high blood pressure in the arteries of the lungs in two different ways [48]. The mechanism of action of macitentan is to stop endothelin (ET)-1 from binding to ETA and ETB. The local ET system is activated in diseases, like PAH, and contributes to organ damage and vascular hypertrophy, or the thickening of the arterial wall. This process is countered by macitentan, which also lowers the chance of hospitalization and clinically worsening occurrences [49]. The enzyme cGMP-specific phosphodiesterase type-5 (PDE-5) is inhibited by tadalafil. This enzyme breaks down the chemical known as cGMP, which relaxes smooth muscles. By blocking PDE-5, individuals with PAH can improve their capacity to exercise by increasing the amounts of cGMP in their smooth muscles, which encourages muscular relaxation and vasodilation [50]. of blood vessels). Severe birth defects, nausea, vomiting, appetite loss, itching, and hypotension are among the side effects. Opsynvi tablets should be kept between 68°F and 77°F (20°C and 25°C) at room temperature [50].

Winrevair (Sotatercept)

Winrevair (17), which was discovered and developed by Merck, got FDA approval on March 24, 2024. Winrevair is an injectable activin-signaling inhibitor [51]. Several TGF-β superfamily ligands, many of which operate on cardiac cells, are bound by it as well. By enhancing the signaling balance and regulating vascular proliferation – the unchecked division of immature cells – this action lowers inflammation and either delays or reverses the structural tissue alterations brought on by PAH, which is used in the management of pulmonary arterial hypertension in adults (PAH, WHO Group 1). Serious adverse effects, such as nosebleeds, vomiting blood, nausea, and dizziness are possible. Refrigerated between 36°F and 46°F (2°C and 8°C) [52].

Vafseo (vadadustat)

Vafseo (18), discovered and developed by Akebia Therapeutics, Inc., got FDA approval on March 27, 2024. Hypoxia-inducible factor (HIF)-prolyl-4-hydroxylases (PH)1, PH2, and PH3 are reversibly inhibited by it, stabilizing the HIF complex and promoting the synthesis of erythropoietin. Renal anemia is improved, and red blood cell production is increased as a result [53]. Serious side effects include cold sweats, chest pain, shortness of breath, and an increased risk of mortality, heart attack, stroke, and blood clots. Store in between 68°F and 77°F (20°C and 25°C) at room temperature [54].

Voydeya (danicopan)

Voydeya (19), discovered and developed by AstraZeneca, got FDA approval on March 29, 2024 [55]. Voydeya specifically binds to complement factor D, an immune system component. It stops it from cleaving into the Ba and Bb fragments needed to create the EVH-related enzyme. Co-administration of eculizumab or ravulizumab aids in the management of intravascular hemolysis (IVH) caused by the membrane attack complex (MAC), which results in the lysis of red blood cells inside blood vessels [56].

Ten to twenty percent of PNH patients who still have clinically significant EVH after receiving a C5 inhibitor are helped by Voydeya. Red blood cells that are destroyed outside of blood vessels are a part of EVH. Because Voydeya contains encapsulated microorganisms, such as *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B, it can have major and perhaps fatal side effects. kept at ambient temperature (68°F to 77°F [20°C to 25°C]) in the original container [57].

Risvan (risperidone)

Risvan (20), discovered and developed by Laboratorios Farmacéuticos Rovi, S.A., got FDA approval on March 29, 2024. It is unclear how precisely risvan and its active metabolite, 9-hydroxy risperidone (paliperidone), affect neurotransmitter levels in schizophrenia, but they block specific brain receptors, including dopamine type 2 (D2) and serotonin type 2 (5HT2) [58]. Adults with schizophrenia may benefit from this extended-release injectable, atypical antipsychotic, which is administered once a month by a medical professional. Serious side effects include tardive dyskinesia, neuroleptic malignant syndrome, metabolic abnormalities, decreased blood cell counts, low blood pressure, seizures, breast soreness or swelling, prolonged erections, and cognitive impairment [59]. It should be stored at room temperature, 20°C to 25°C (68°F to 77°F), with excursions permitted between 15°C and 30°C (between 59°F and 86°F) in the unopened original packaging [60].

Zevtera (ceftobiprole medocaril)

Zevtera (21), discovered and developed by Basilea Pharmaceutica Ltd., got FDA approval on April 3, 2024. Zevtera functions by stopping the bacterial cell wall from forming, which kills the germs. It accomplishes this by attaching to penicillin-binding proteins (PBPs) that are necessary and blocking the action of an enzyme that is necessary for the bacterial cell wall's peptidoglycan layer to develop. PBP2a in methicillin-resistant *S. aureus*, PBP2x and PBP2b in penicillin-resistant *Streptococcus pneumoniae*, and *S. aureus* PBPs 1–4 are only a few of the PBPs that Zevtera has a strong affinity for and are frequently linked to bacterial resistance [61]. Zevtera should only be used to treat or prevent infections that are clearly or highly suspected to be caused by bacteria to lower the possibility of resistance and preserve the effectiveness of antibiotics [62]. It results in severe hypersensitivity reactions, Clostridium difficile-associated diarrhea (CDAD), and an elevated risk of death in patients with ventilator-associated bacterial pneumonia (VABP). After being reconstituted, Zevtera needs to be used right away. The reconstituted solution can be kept at room temperature for up to one hour or chilled for up to 24 hours at 2°C to 8°C [63].

Xromi (hydroxyurea)

Xromi (22), discovered and developed by Nova Laboratories, Ltd., got FDA approval on April 4, 2024 [64]. It is an oral medication that can help children with sickle cell anemia who suffer repeated moderate to severe painful crises between the ages of six months and under two years old by decreasing the frequency of these episodes and the requirement for blood transfusions. It has been demonstrated to raise fetal hemoglobin (HbF) levels, lower neutrophil counts, raise red blood cell water content, exacerbate sickle cell deformities, and alter RBC adhesion to the endothelium [65]. Serious adverse effects include hemolytic anemia, gangrene, low blood cell counts, and an increased risk of cancer. Keep Xromi refrigerated between 35°F and 46°F (2°C and 8°C) in a spotlessly clean area of the refrigerator [66].

Selarsdi (ustekinumab-aekn)

Selarsdi (23), discovered and developed by Alvotech and Teva Pharmaceuticals, got FDA approval on April 16, 2024 [67]. This biosimilar to Stelara, an injectable human interleukin-12 and -23 inhibitor, can be used to treat active psoriatic arthritis and moderate to severe plaque psoriasis. It selectively attaches to the p40 protein subunit, which is required for the cytokine's interleukin 12 and interleukin 23. Numerous cells, including lymphocytes, monocytes, and macrophages, produce interleukins, which are implicated in immunological and inflammatory responses, including inflammation brought on by autoimmune diseases [68]. Selarsdi decreases swelling, discomfort, inflammation, and skin complaints

by inhibiting the action of IL-12 and IL-23. Serious side effects from selarsdi include severe infections, pneumonia, PRES syndrome (a brain-related illness), headaches, runny noses, nasal congestion, and sore throats. Stored Selarsdi prefilled syringes in a refrigerator between 36°F to 46°F (2°C to 8°C) [69].

Lumisight (Pegulicianine)

Lumisight (24), discovered and developed by Lumicell, Inc., got FDA approval on April 17, 2024 [70]. When the original specimen is removed during lumpectomy surgery, it is employed as an optical imaging agent recommended for fluorescence imaging in adults with breast cancer as a supplement for the intraoperative detection of malignant tissue within the resection cavity [71]. A fluorescent imaging medication called Lumisight is used during breast cancer surgery to assist in identifying malignant tissue when the primary cancer specimen is removed during a lumpectomy procedure [72]. Lumisight fluoresces when it is in or near tumor cells, and this fluorescence can be viewed with an imaging system like the Lumicell Direct Visualization System (DVS). During surgery, any tissue found to be cancerous can be excised to eradicate the cancerous tissue as completely as possible. Atypical urine color, hypersensitivity reactions, pruritus, urticaria, hypotension, lip swelling, erythema, anxiety, chest pain, cyanosis, headache, dizziness, dyspnea, maculopapular rash, nausea, paresthesia, visual abnormalities, and vomiting are the most frequent side effects of Lumisight. An intravenous (IV) injection of Lumisight is administered over a 3-minute period. It is given between two and six hours before imaging. Vials should be kept frozen between –25°C and –15°C (–13°F and 5°F) in their original carton to keep light out [73].

Rezenopy Nasal Spray (naloxone hydrochloride)

Rezenopy Nasal Spray (25), discovered and developed by Summit Biosciences Inc., got FDA approval on April 19, 2024. It is used to treat adults and children who have breathing difficulties, extreme tiredness, or are unable to respond temporarily to an opioid overdose or suspected opioid overdose [74]. By competing for the same receptor sites as opioids, it counteracts their effects. This counteracts the drowsiness, hypotension, and breathing difficulties caused by opioids. Additionally, it can reverse the unpleasant and mind-altering effects of medications like pentazocine [75]. Serious adverse effects from Rezenopy nasal spray include abrupt opioid withdrawal symptoms, aches and pains in the body, agitation or restlessness, elevated blood pressure or heart rate, cramping in the stomach, or diarrhea. Store Rezenopy nasal spray either in the refrigerator or at room temperature between 2°C to 25°C (36°F to 77°F) [76].

Anktiva (Nogapendekin alfainbakicept-pmln)

Anktiva (26), discovered and developed by ImmunityBio, Inc., got FDA approval on April 22, 2024. For bladder cancer forms that have not responded to BCG (Bacillus Calmette-Guérin) vaccine treatment, Anktiva is a cancer immunotherapy [77]. Anktiva stimulates the immune system, particularly immunological memory cells, to destroy bladder cancer cells when combined with the BCG vaccine. This might facilitate a long-lasting, full response in the patient. Anktiva is an IL-15 agonist (nogapendekin alfa inbakicept-PMLN). It is used to treat carcinoma in situ (CIS) in cases of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), either with or without papillary tumors. Anktiva is administered as an intravenous instillation together with BCG, a liquid medication that enters the bladder via the urethra and is delivered using a catheter [78]. Urinary pain, frequent urination, urgency, blood in the urine, urinary tract infection, chills, fever, and pain in the muscles and joints are the most frequent side effects. Vials should be kept refrigerated between 2°C and 8°C (36°F and 46°F) in their original carton to prevent light deterioration [79].

Ojemda (Tovorafenib)

Ojemda (27), discovered and developed by Day One Biopharmaceuticals, Inc., got FDA approval on April 22, 2024. A medication called ojemda is used to treat pediatric low-grade gliomas (pLGGs); it may aid in tumor shrinkage or stabilization [80]. When a patient has a BRAF fusion or rearrangement, also known as a BRAF V600 mutation, and their cancer has not responded to treatment or has relapsed

after prior therapy, Ojemda (tovorafenib) is prescribed. The most common brain tumor in children to be diagnosed is pediatric low-grade gliomas [81]. A protein known as Type II RAF kinase is blocked by the type II pan-RAF kinase inhibitor ojemda. Rash, changes in hair color, exhaustion, viral infection, vomiting, headache, fever, dry skin, constipation, nausea, dermatitis acneiform, upper respiratory tract infections, and bleeding are among the most frequent side effects. Store at 20°C to 25°C (68°F to 77°F) [82].

Pivya (pivmecillinam)

Pivya (28), discovered and developed by Utility Therapeutics Ltd., got FDA approval on April 24, 2024. Pivya is a beta-lactam antibiotic that functions by obstructing the bacterial cell wall's biosynthesis [83]. It is a pro-drug that is digested by the body's digestive system, bloodstream, and other tissues' enzymes to produce mecillinam, an active antibacterial agent. It is an oral penicillin-type antibiotic that can be used to treat females 18 years of age and older who have simple UTIs caused by susceptible isolates of Proteus mirabilis, Escherichia coli, and Staphylococcus saprophyticus [84]. Anaphylaxis, drug reactions with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome, nausea, and diarrhea are the most frequent adverse effects. Tablets should be kept in their original packet at room temperature, between 20°C and 25°C (59°F and 86°F) [85].

Hercessi (trastuzumab-strf)

Hercessi (29), discovered and developed by Accord BioPharma, Inc., got FDA approval on April 25, 2024 [86]. The FDA has approved Hercessi, the sixth biosimilar to Herceptin, for the treatment of specific HER2+ (Human Epidermal Growth Factor Receptor 2-Positive) cancers, including HER2-overexpressing breast cancer and gastric or gastroesophageal junction adenocarcinoma. Since hercessi targets malignancies with high levels of the receptor protein HER2, it is a targeted treatment rather than chemotherapy. Tumors are believed to originate when HER2 instructs cells to proliferate and divide quickly [87]. Hercessi is believed to target and adhere to these receptors to both instruct the body's immune system to attack the cell and prevent the growth and cell division of human tumor cells that express HER2. Hercessi can impact normal cells and cause negative effects because normal cells also contain HER2, albeit in smaller amounts. Breathlessness or coughing, dizziness, intense headaches, impaired vision, blisters, or oral ulcers are a few adverse effects. stored in the original box and refrigerated between 2°C and 8°C (36°F and 46°F) until reconstitution time [88].

Libervant (diazepam)

Libervant (30), discovered and developed by Aquestive Therapeutics, Inc., got FDA approval on April 26, 2024 [89]. For children ages 2 to 5 who experience seizure clusters, commonly referred to as "acute repetitive seizures," which deviate from their typical seizure pattern, Libervant is an oral benzodiazepine film that may be taken for a brief period. Since diazepam binds at the benzodiazepine site of the GABAA receptor, it is thought that it enhances GABA, an inhibitory neurotransmitter, which helps treat seizure clusters [90]. Libervant includes diazepam, which has the potential to be abused or create dependence, making it a federally prohibited substance (C-IV) [91]. When stopped abruptly, it may result in severe adverse effects, such as respiratory issues, extreme sleepiness, and withdrawal symptoms. kept between 68°F and 77°F (20°C and 25°C) at room temperature [92].

Xolremdi (mavorixafor)

Xolremdi (31), discovered and developed by X4 Pharmaceuticals, got FDA approval on April 26, 2024 [93]. An oral CXC chemokine receptor 4 antagonist can be used to treat adults and children with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) who are 12 years of age and older by increasing the number of mature neutrophils and lymphocytes in the bloodstream [94]. Inhibiting CXCR4 receptors, it helps fight infections and HPV-related warts by releasing immune cells that have been confined in the bone marrow into the bloodstream. But more than 10% of users experience serious adverse effects from Xolremdi, such as low platelet counts, rash, nasal problems, nosebleeds, vomiting, and dizziness. Drugs that lengthen QTc intervals and those metabolized by

CYP2D6 enzymes interact negatively with them; therefore, careful monitoring and modification are required [95]. It should be taken orally on an empty stomach once a day, before breakfast. Overall, Xolremdi treats the immune cell retention that underlies WHIM syndrome, but because of its adverse effect profile and potential for drug interactions, it should be used with caution. kept between 2°C and 8°C (36°F and 46°F) in the refrigerator [96].

Beqvez (fidanacogene elaparvovec-dzkt)

Beqvez (32), discovered and developed by Pfizer Inc., got FDA approval on April 26, 2024 [97]. Adult males with moderate to severe hemophilia B, it is a one-time gene therapy. It is appropriate for people who are on prophylactic factor IX, have experienced significant bleeding in the past, and do not have antibodies against the AAVRh74var capsid [98]. To enable patients to create factor IX on their own, the therapy delivers a high-activity factor IX gene to liver cells via a viral vector. Beqvez can have major adverse effects, such as liver damage, hypersensitivity, and a possible increased risk of liver cancer, when administered as a 60-minute infusion. Patients need to have annual liver exams for five years as well as frequent monitoring, particularly during the first four months. It is essential to store materials properly at extremely low temperatures, between –90 °C and –60 °C (–130 °F and –76 °F) [99].

Myhibbin (mycophenolate mofetil)

Myhibbin (33), discovered and developed by Azurity Pharmaceuticals, Inc., got FDA approval on May 1, 2024 [100]. For transplant patients three months of age and up, myhibbin, a suspension of mycophenolate mofetil, is used to avoid organ rejection. It inhibits DNA synthesis and stops cell development in conjunction with cyclosporine and corticosteroids by transforming into mycophenolic acid in the body [101]. Serious adverse effects include infections, gastrointestinal problems, and low blood cell counts. Frequent adverse effects include nausea, dizziness, diarrhea, and blood sugar swings; youngsters may also have fever and stomach pain. Myhibbin raises the risk of serious infections, such as PML and viral reactivation, cancer, birth abnormalities, and miscarriages [102]. kept in storage between 68°F and 77°F (20°C and 25°C) [103].

Imdelltra (tarlatamab-dlle)

Imdelltra (34), discovered and developed by Amgen, got FDA approval on May 16, 2024. For people with extensive-stage small cell lung cancer (ES-SCLC) who are not responding to platinum-based chemotherapy, it is an injectable cancer treatment [104]. It targets cancer cells by triggering the immune system. Cytokine release syndrome (CRS), low blood cell counts, infections, liver damage, allergic reactions, and neurological problems are examples of serious side effects. Fatigue, fever, ill taste, decreased appetite, muscle soreness, constipation, and nausea are typical adverse effects. Before and during treatment, patients must have routine blood testing [105]. Under refrigeration, Imdeltra should be kept between 20°C and 25°C (68°F and 77°F) and protected from light [106].

Opuviz (aflibercept-yszy)

Opuviz (35), discovered and developed by Samsung Bioepis Co. Ltd., got FDA approval on May 20, 2024 [107]. It is an injectable drug for the eyes that is given by a medical professional every one to two months to treat various eye problems, such as diabetic retinopathy (DR), macular edema after retinal vein occlusion (RVO), wet age-related macular degeneration (AMD), and DME [108]. Allergies, inflammation of the eyes, retinal detachment, infections, and elevated intraocular pressure are examples of serious side effects. Common adverse effects include red or watery eyes, impaired vision, swollen eyelids, mild discomfort, ruptured blood vessels in the eye, eye pain, cataracts, vitreous detachment, floaters, and elevated eye pressure [109]. Store it in the refrigerator at 2°C to 8°C (36°F to 46°F) and protect it from light [110].

Yesafili (aflibercept-jbvf)

Yesafili (36), discovered and developed by Biocon Biologics Inc. Ltd., got FDA approval on May 20, 2024 [111]. This injectable medicine is used once every two months to treat diabetic retinopathy (DR), macular edema after retinal vein occlusion (RVO), wet age-related macular degeneration (AMD), and DME. Since it is biosimilar to Eylea, there aren't any appreciable variations in terms of efficacy or safety. Yesafili, when administered by a medical professional, prevents aberrant blood vessel growth in the retina by blocking vascular endothelial growth factor (VEGF). Ocular discomfort, conjunctival bleeding, cataracts, vitreous separation, floaters, and elevated intraocular pressure are typical adverse effects. Allergies, inflammation, retinal detachment, infections, and elevated intraocular pressure are examples of serious adverse effects. Store Yesafili in the refrigerator at 2°C to 8°C (36°F to 46°F) and use only as directed by your doctor [112].

Onyda XR (Clonidine hydrochloride)

Onyda XR (37), discovered and developed by Tris Pharma, Inc., got FDA approval on May 26, 2024 [113]. It is a once-daily drug used to treat children six years of age and up for symptoms of ADHD. It can be taken either on its own or with other ADHD drugs. Onyda XR can lessen hyperactivity, impulsivity, and inattentiveness by activating α-2 adrenergic receptors in the brain, though its precise mechanism in ADHD is unclear [114]. Tiredness, drowsiness, irritability, difficulty falling asleep, nightmares, constipation, and dry mouth are typical side effects. Severe adverse effects, including fainting, a slow heartbeat, or chest pain, need to be treated right away. Without a doctor's consent, Onyda XR should not be used in children under 6 or by pregnant or nursing mothers due to potential reproductive effects. Oral administration is done before bed, with dosages modified according to each person's response. Proper storage at 20°C to 25°C (68°F to 77°F) in a cool, dark place and careful monitoring of interactions with other drugs are essential [115].

Bkemv (eculizumab-aeeb)

Bkemv (38), discovered and developed by Amgen Inc., got FDA approval on May 28, 2024 [116]. Adults and children with blood problems can be treated with this injectable medicine. This biosimilar to Soliris prevents the destruction of red blood cells in paroxysmal nocturnal hemoglobinuria (PNH) and thrombotic microangiopathy (TMA) associated with atypical hemolytic uremic syndrome (aHUS) by inhibiting the complement system, a component of the immune system. Due to possible serious adverse effects, this medicine is given intravenously and needs to be well monitored [117]. These include a higher chance of developing additional infections, infusion-related complications, and serious infections, including meningococcal illness. Prior to beginning treatment, patients must have a meningococcal vaccination and undergo continuous monitoring. Headaches, infections, back pain, nausea, and other common side effects are common and should be treated right away, but more serious symptoms, like chest pain or breathing difficulties, should be seen by a doctor right away [118]. To manage treatment and any problems, close communication with healthcare practitioners is necessary. Keep chilled between 2°C and 8°C (36°F and 46°F) [119].

mRESVIA (respiratory syncytial virus vaccine, mRNA)

mRESVIA (39), discovered and developed by Moderna, Inc., got FDA approval on May 31, 2024. It is an injectable vaccination meant to guard against respiratory syncytial virus (RSV)-related lower respiratory tract illness in individuals sixty years of age and older. It stimulates the immune system to create antibodies against RSV by means of modified RNA technology [120]. Unlike prior vaccinations, like Arexvy and Abrysvo, mRESVIA is the first modified RNA vaccine for RSV. More than 10% of patients report common adverse effects, which include soreness around the injection site, exhaustion, headaches, pain in the muscles and joints, and tightness beneath the arms [121]. Although uncommon, serious allergic reactions can occur and necessitate monitoring following immunization [122].

Rytelo (imetelstat)

Rytelo (40), discovered and developed by the Geron Corporation biopharma company, got FDA approval on June 6, 2024. Adults with severe anemia necessitating frequent blood transfusions and low- to intermediate-risk myelodysplastic syndromes (MDS) can benefit from this injectable therapy. Rytelo functions by blocking telomerase, an enzyme that cancerous stem cells need to replicate their cells. Cell death results from this reduction in telomere length [123]. Increased liver enzymes, weariness, joint discomfort, and decreased platelet and white blood cell counts are common side effects that impact over 10% of users [124]. Severe reactions to infusions and reduced immunity, which increase the risk of infections and bleeding, are examples of serious hazards. To ensure safety and efficacy, storage must be refrigerated, and careful reconstitution and handling must occur prior to administration. Vials should be kept chilled between 2°C and 8°C (36°F and 46°F) [125].

Iqirvo (elafibranor)

Iqirvo (41), discovered and developed by Ipsen Biopharmaceuticals, got FDA approval on June 10, 2024. This oral tablet is used once a day to treat primary biliary cholangitis (PBC). It can be taken with or without food and is frequently administered in addition to ursodeoxycholic acid (UDCA) for individuals who are intolerant to or have not reacted well to UDCA alone. Iqirvo may lower alkaline phosphatase levels without worsening liver damage by activating certain receptors (PPAR-alpha and PPAR-delta) that control energy and metabolic processes [126]. Weight gain, stomach discomfort, diarrhea, and muscular problems are typical adverse effects. Allergic responses, myopathy, and abnormalities of the liver are serious hazards [127]. Iqirvo should be kept out of direct sunlight and at room temperature [128].

Table 1. FDA-approval date, indications and company discovered.

S. N.	FDA Approval Date	Drug Name	Indications	Company
1.	05-01-2024	Zelsuvmi (berdazimer sodium)	Treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.	Ligand Pharmaceuticals Incorporated
2.	09-02-2024	Eohilia (budesonide)	Treatment of eosinophilic esophagitis.	Takeda Pharmaceutical Company Limited
3.	13-02-2024	Aurlumyn (iloprost)	Treatment of severe frostbite in adults to reduce the risk of digit amputations.	Eicos Sciences Inc.
4.	16-02-2024	Amtagvi (lifileucel)	Treatment of adult patients with unresectable or metastatic melanoma.	Iovance Biotherapeutics, Inc.
5.	22-02-2024	Exblifep (cefepime & enmetazobactam)	Treatment of complicated Urinary tract infections	Allecra Therapeutics
6.	23-02-2024	Simlandi (adalimumab-ryvk)	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa, Uveitis	Alvotech and Teva Pharmaceutical Industries Ltd.
7.	29-02-2024	Letybo (letibotulinumtoxinA-wlbg)	It temporarily improves the appearance of moderate to severe glabellar line	Hugel, Inc.
8.	05-03-2024	Jubbonti (denosumab-bbdz)	Treatment of osteoporosis.	Sandoz
9.	05-03-2024	Wyost (denosumab-bbdz)	Treatment of Osteolytic Bone Lesions of Multiple Myeloma, Osteolytic Bone Metastases of Solid Tumors, Giant Cell Tumor of Bone, Hypercalcemia of Malignancy	Sandoz
10.	05-03-2024	Tyenne (tocilizumab-aazg)	Treatment of rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis.	Fresenius Kabi

11.	13-03-2024	Tevimbra (tislelizumab-jsgr)	Treatment of metastatic esophageal squamous cell carcinoma	BeiGene, Ltd.
12.	14-03-2024	Rezdiffra (resmetirom)	Treatment of non-cirrhotic, non-alcoholic steatohepatitis with moderate to advanced liver scarring	Madrigal Pharmaceuticals, Inc.
13.	18-03-2024	Lenmeldy (atidarsagene autotemcel)	Treatment of children with metachromatic leukodystrophy (MLD).	Orchard Therapeutics
14.	19-03-2024	Tryvio (aprocitentan)	Treatment of hypertension	Idorsia Ltd.
15.	21-03-2024	Duvyzat (givinostat)	Treatment of Duchenne Muscular Dystrophy	Italfarmaco Group
16.	22-03-2024	Opsynvi (macitentan and tadalafil)	Treatment of pulmonary arterial hypertension.	Actelion Pharmaceuticals US, Inc.
17.	26-03-2024	Winrevair (sotatercept)	Treatment of pulmonary arterial hypertension	Merck
18.	27-03-2024	Vafseo (vadadustat)	Treatment of anemia due to chronic kidney disease	Akebia Therapeutics, Inc.
19.	29-03-2024	Voydeya (danicopan)	Treatment of paroxysmal nocturnal hemoglobinuria	AstraZeneca
20.	29-03-2024	Risvan (risperidone)	Treatment of schizophrenia in adults.	Laboratorios Farmacéuticos Rovi, S.A.
21.	03-04-2024	Zevtera (ceftobiprole medocaril)	Treatment of bacteremia, skin and structure infection, pneumonia	Basilea Pharmaceutica Ltd.
22.	04-04-2024	Xromi (hydroxyurea)	Treatment of sickle cell anemia	Nova Laboratories, Ltd.
23.	16-04-2024	Selarsdi (ustekinumab-aekn)	Treatment of plaque psoriasis and psoriatic arthritis.	Alvotech and Teva Pharmaceuticals
24.	17-04-2024	Lumisight (pegulicianine)	Treatment of diagnosis and investigation	Lumicell, Inc.
25.	19-04-2024	Rezenopy (naloxone hydrochloride)	Emergency treatment of Opioid Overdose	Summit Biosciences Inc.
26.	22-04-2024	Anktiva (nogapendekin alfa inbakicept-pmln)	Treatment of BCG-unresponsive non-muscle invasive bladder cancer.	ImmunityBio, Inc.
27.	23-04-2024	Ojemda (tovorafenib)	Treatment of relapsed or refractory pediatric low-grade glioma.	Day One Biopharmaceuticals, Inc.
28.	24-04-2024	Pivya (pivmecillinam)	Treatment of uncomplicated urinary tract infections.	Utility Therapeutics Ltd.
29.	25-04-2024	Hercessi (trastuzumab-strf)	Treatment of breast and gastric or gastroesophageal junction adenocarcinoma.	Accord BioPharma, Inc.
30.	26-04-2024	Libervant (diazepam)	Treatment of seizure clusters in children aged 2 to 5 years.	Aquestive Therapeutics, Inc.
31.	26-04-2024	Xolremdi (mavorixafor)	Treatment of WHIM syndrome.	X4 Pharmaceuticals
32.	26-04-2024	Beqvez (fidanacogene elaparvovec-dzkt)	Treatment of hemophilia B.	Pfizer Inc.
33.	01-05-2024	Myhibbin (mycophenolate mofetil)	Treatment of prophylaxis of organ rejection.	Azurity Pharmaceuticals, Inc.
34.	16-05-2024	Imdelltra (tarlatamab-dlle)	Treatment of extensive stage small cell lung cancer.	Amgen
35.	20-05-2024	Opuviz (aflibercept-yszy)	Treatment of macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy	Samsung Bioepis Co., Ltd.
36.	20-05-2024	Yesafili (aflibercept-jbvf)	Treatment of macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy	Biocon Biologics Inc
37.	24-05-2024	Onyda XR (clonidine hydrochloride)	Treatment of attention-deficit/hyperactivity disorder (ADHD) in children aged six years and older.	Tris Pharma, Inc.
38.	28-05-2024	Bkemv (eculizumab-aeeb)	Treatment of paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome.	Amgen Inc.

39.	31-05-2024	mRESVIA (respiratory syncytial virus vaccine, mRNA)	Treatment of RSV	Moderna, Inc.
40.	06-06-2024	Rytelo (imetelstat)	Treatment of low- to intermediate-1 risk myelodysplastic syndromes	Geron Corporation biopharma company
41.	10-06-2024	Iqirvo (elafibranor)	Treatment of primary biliary cholangitis in combination with ursodeoxycholic acid	Ipsen Biopharmaceuticals

CONCLUSIONS

The FDA's approval of new drugs in 2024 reflects a year of remarkable progress and innovation in the pharmaceutical industry. These newly approved therapies demonstrate significant advancements in addressing complex and diverse medical conditions, offering hope and improved quality of life to many patients. From novel mechanisms of action to enhanced safety and efficacy profiles, these drugs represent the forefront of medical research and development. The approvals span various therapeutic areas, showcasing the industry's dedication to tackling both common and rare diseases. The advancements in cardiovascular, infectious, neurological, and oncological treatments illustrate the breadth and depth of innovation driving the sector forward. As we reflect on these achievements, it is evident that continued investment in research and clinical trials is crucial for sustaining this momentum. In summary, the drugs approved by the FDA in 2024 signify a year of substantial progress, setting new standards for treatment and care. These advancements pave the way for future innovations, promising a brighter and healthier future for patients worldwide.

Author Contribution Statement

Komal G. Sangu – conceptualizing the overall theme and structure of the review article, Literature Search and Data Collection, Writing and Drafting; *Shweta R. Gupta* – Literature Search and Data Collection; *Pranita D. Shigwan* – Literature Search and Data Collection; *Kajal S. Prajapati* – Literature Search and Data Collection; *Anchal P. Verma* – Literature Search and Data Collection.

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