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New Drug Update February 2024

ADURS

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San Diego, California

Statement of Disclosure

- ✓ I have no relevant conflicts of interest to report
- ✓ This presentation will include a discussion of unlabeled or investigational use of therapies that have not yet been approved by the FDA
- ✓ This presentation will focus on therapies approved by the FDA within the last year; this is not an all-inclusive review of new drugs approved in the past year

Learning Objectives

At the conclusion of this educational activity, participants will be able to:

Describe important considerations for therapies approved by the FDA within the last year regarding patient selection, dose, and administration.

List notable therapies approved by the FDA within the last year and their indications for use.

Identify novel therapies with limited therapeutic alternatives.

Learning Assessment Questions

True or False?

(exagamglogene autotemcel) is indicated for Hemophilia A.

Which of the following are important considerations for Zurzuvae (zuranolone)?

1. Faster onset of action compared to traditional antidepressant therapy
2. Use alone or as an adjunct to oral antidepressant therapy
3. Boxed warning regarding hazardous activities due to CNS depressant effects
4. All of the above

True or False?

Beyfortus (nirsevimab) should not be given if the pregnant patient received Abrysvo more than 2 weeks prior to Beyfortus administration.

Our Discussion Today

1. Overview of FDA New Drug Approval Patterns
2. Gene and Cell Therapy Products
3. Oncology
4. Neurology
5. Diabetes/Cardiology/Nephrology
6. Rare Diseases
7. Infectious Disease
8. Immunomodulators
9. Other Conditions
10. Biosimilars

Bethany Holderread, Pharm.D.

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Bethany assists Mercer's Medicaid clients with the management of pharmacy benefits.

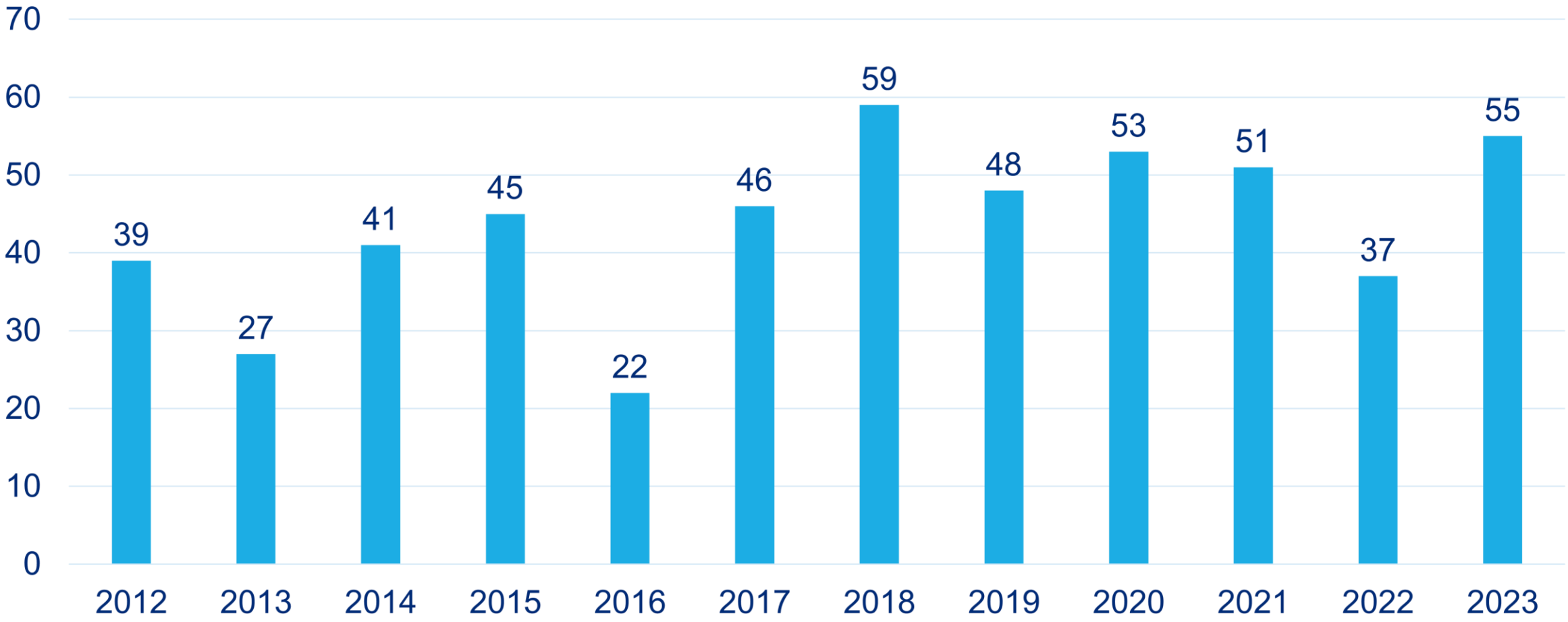
1
Overview of FDA New Drug Approval Patterns

Random Food Fact 1:

There are 40 billion Oreo cookies made each year. If you stacked them all together, the cookies would encircle the earth five times.

Sanchez. https://www.thedailymeal.com/eat/weird-food-facts/

FDA Approval Trends: New Molecular Entities



FDA. New Drug Therapy Approvals. https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products. Accessed 01/03/2024.

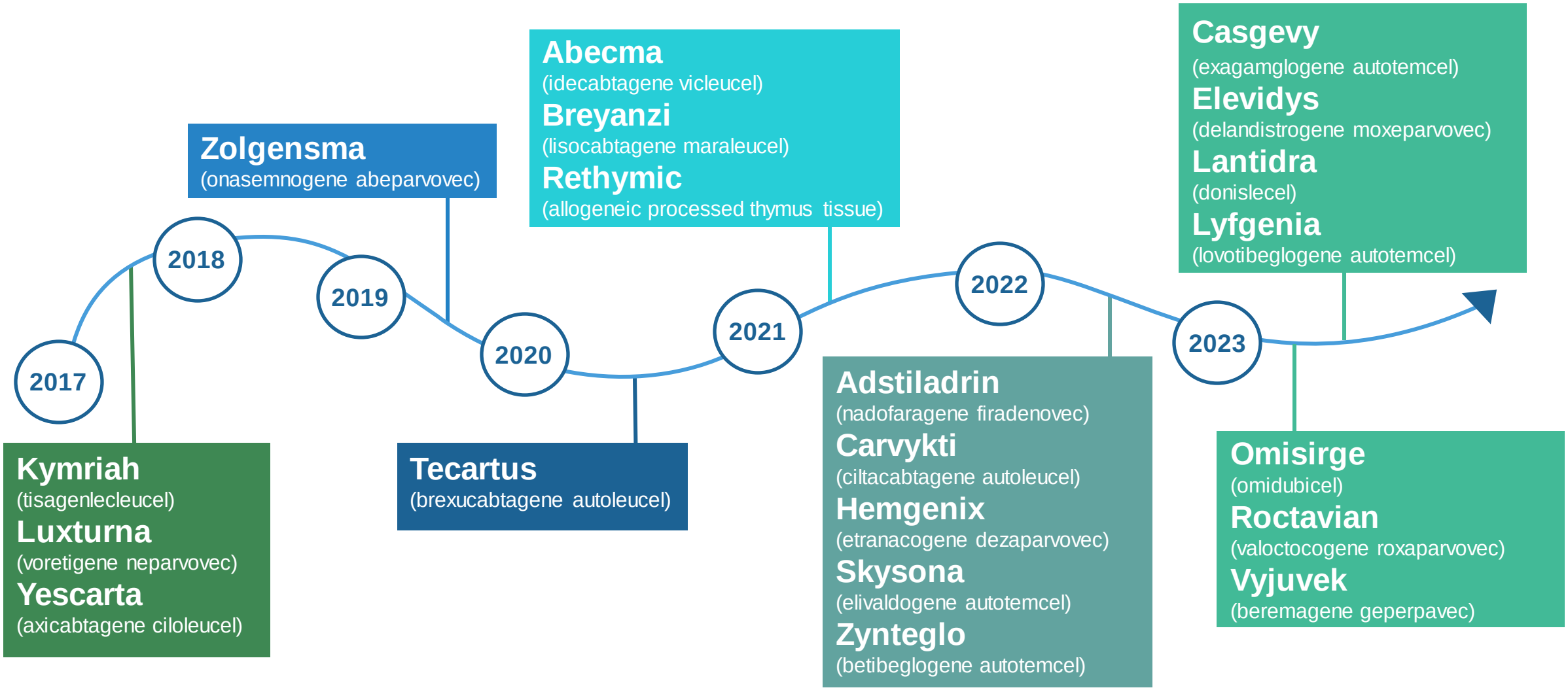
Summary of 2022 Novel Approvals

At Least One Expedited Development or Review Method: 65%

First-in-Class 54%	Orphan 54%	Fast Track 32%
Breakthrough Therapy 35%	Priority Review 57%	Accelerated Approval 16%

FDA. New Drug Therapy Approvals. https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products. Accessed 06/12/2023.

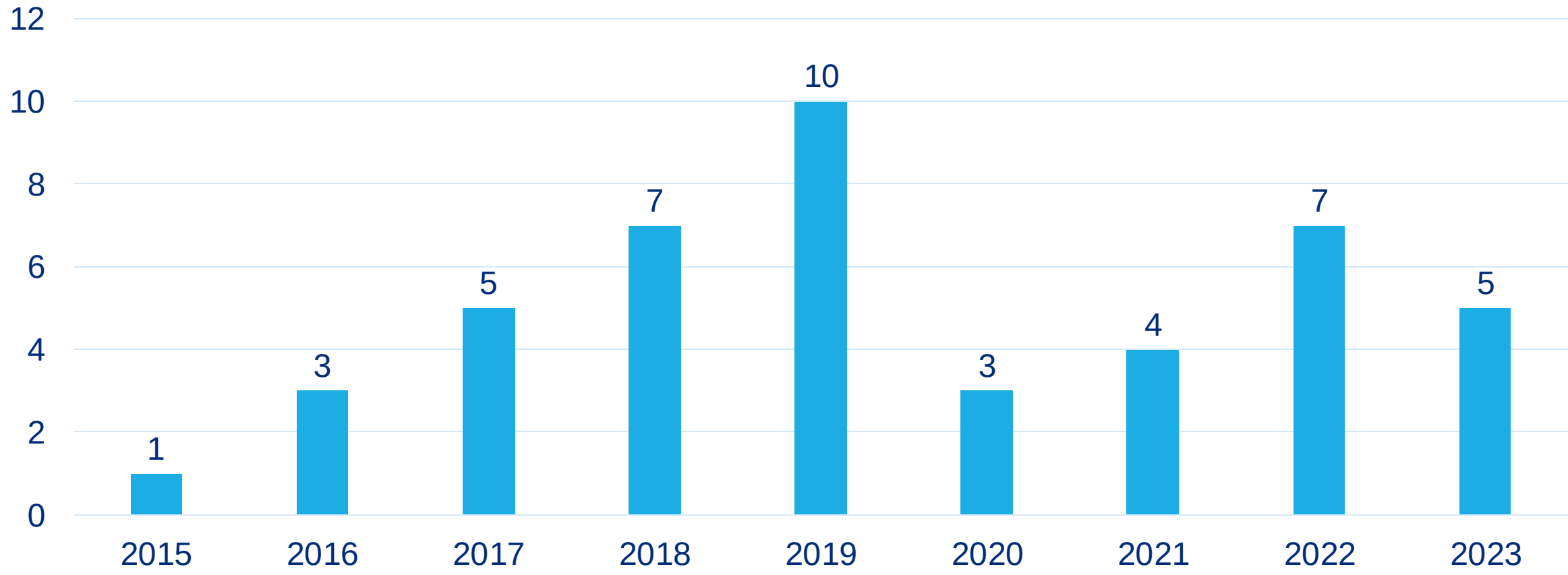
Approved Gene and Cell Therapy Products



FDA. Approved Cellular and Gene Therapy Products. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products Accessed 1/02/2024. **Note**: Imlygic (talimogene laherparepvec) and Provenge (sipuleucel-T) not included on timeline. Products approved prior to 2017 not included.

Biosimilar Approvals

FDA has approved a total of 45 biosimilar products for 14 different reference products since 2015



FDA. FDA-Approved Biosimilar Products. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed 01/02/2024.

2
Gene and Cell Therapy Products

Random Food Fact 2:

Many people don't know that Cheetos' signature orange cheese "dust" that gets left behind on your fingers actually has a name. That powdery substance is called "cheetle."

Sanchez. https://www.thedailymeal.com/eat/weird-food-facts/

2023 Gene and Cell Therapy Products

Drug Name	Approval Date	Indication
Casgevy (exagamglogene autotemcel)	Dec 2023	Sickle cell disease (SCD)
Lyfgenia (lovotibeglogene autotemcel)	Dec 2023	SCD
Elevidys (delandistrogene moxeparvovec)	June 2023	Duchenne muscular dystrophy (DMD)
Lantidra (donislecel)	June 2023	Type 1 diabetes
Roctavian (valoctocogene roxaparvovec)	June 2023	Hemophilia A
Vyjuvek (beremagene geperpavec)	May 2023	Wounds in patients with dystrophic epidermolysis bullosa
Omisirge (omidubicel)	April 2023	Following myeloablative conditioning to reduce the time to neutrophil recovery

FDA. Approved Cellular and Gene Therapy Products. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products. Accessed 01/03/2024.

Elevidys (delandistrogene moxeparvovec)

Indication	Duchenne muscular dystrophy (DMD)
Market Landscape	• Estimated U.S. prevalence ranges between 10,000 and 15,000 males • First gene therapy for ambulatory DMD patients 4-5 years of age • Current treatment consists of exon skipping therapies and glucocorticoids
Clinical Studies	• 41 patients aged 4 to 7 years with mutation between exons 18 to 58 • Results found change in dystrophin levels; ambulatory data conflicting
Dosing	One-time, single IV dose
Important Considerations	• Approval in a narrower population, rather than age range of patients studied in clinical trials • Contraindicated in patients with deletion in exon 8 or exon 9 in DMD gene • Baseline testing for the presence of anti-AAVrh74 • Liver monitoring, myocarditis, and immune-mediated myositis
Cost	$3.2 million for one-time treatment

FDA. Elevidys. Accessed 07/2023.
IPD Analytics. Elevidys Update.

Casgevy (exagamglogene autotemcel)

Indication	SCD in patients ≥ 12 with recurrent vaso-occlusive crises (VOCs)
Market Landscape	• Estimated 100,000 patients with SCD in the United States • Manufacturer estimates 32,000 patients with SCD or TDT eligible • Current treatments consist of stem cell transplant, increasing hemoglobin levels, or symptomatic relief; cost range $2,000 to $120,000 annually
Clinical Studies	SCD patients 12 to 35 years of age: 29 of 31 patients (93.5%) achieved freedom from severe VOC episodes for at least 12 consecutive months
Dosing	One-time IV infusion
Important Considerations	• Myeloablative conditioning must be administered before infusion • HIV-1/HIV-2, hepatitis B virus, and hepatitis C virus screening required • No reported cases of insertional oncogenesis associated with Casgevy
Cost	• $2.2 million for the one-time treatment (does not include hospital stay or other medications required prior to treatment) • ICER: cost-effective if priced at up to $2.05 million per treatment

FDA. Casgevy. Accessed 1/2024.
IPD Analytics. Casgevy Update.

Lyfgenia (lovotibeglogene autotemcel)

Indication	Patients ≥ 12 years with SCD & history of vaso-occlusive events (VOEs)
Market Landscape	• Similar to Casgevy • Manufacturer estimates 20,000 patients eligible
Clinical Studies	SCD patients 12 to 50 years of age: 28 of 32 patients (88%) experienced a complete resolution of VOEs between 6 and 18 months after infusion
Dosing	One-time IV infusion
Important Considerations	• Myeloablative conditioning must be administered before infusion • HIV-1/HIV-2screening required • Patients with α-thalassemia trait may experience anemia that may require chronic red blood cell transfusions • Lifelong monitoring for malignancies
Cost	• $3.1 million for the one-time treatment (does not include hospital stay or other medications required prior to treatment) • ICER: cost-effective if priced at up to $2.05 million per treatment

FDA. Lyfgenia. Accessed 1/2024.
IPD Analytics. Lyfgenia Update.

3
Oncology

Random Food Fact 3:

Illinois is home to the world's largest bottle of ketchup. It even has its own festival in the summer.

Blee. https://spoonuniversity.com/lifestyle/51-state-food-facts

Novel 2023 Oncology Approvals

Drug Name	Approval Date	Indication
Ogsiveo (nirogacestat)	Nov 2023	Desmoid tumors
Truqap (capivasertib)	Nov 2023	Breast cancer
Ryzneuta (efbemalenograstim alfa)	Nov 2023	Neutropenia
Augtyro (repotrectinib)	Nov 2023	Non-small cell lung cancer
Fruzaqla (fruquintinib)	Nov 2023	Refractory, metastatic colorectal cancer
Loqtorzi (toripalimab)	Oct 2023	Recurrent or metastatic nasopharyngeal carcinoma
Ojjaara (momelotinib)	Sept 2023	Myelofibrosis in adults with anemia
Aphexda (motixafortide)	Sept 2023	To mobilize hematopoietic stem cells for collection and transplantation in multiple myeloma patients
Elrexfio (elranatamab)	Aug 2023	Relapsed or refractory multiple myeloma
Talvey (talquetamab)	Aug 2023	Relapsed or refractory multiple myeloma
Vanflyta (quizartinib)	July 2023	Newly diagnosed acute myeloid leukemia

FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed 01/03/2024.

Novel 2023 Oncology Approvals (2)

Drug Name	Approval Date	Indication
Columvi (glofitamab)	June 2023	Diffuse large B-cell lymphoma (DLBCL)
Posluma (flotufolastat F 18)	May 2023	To use with positron emission tomography imaging in prostate cancer
Epkinly (epcoritamab)	May 2023	Relapsed or refractory DLBCL
Zynyz (retifanlimab)	Mar 2023	Metastatic or recurrent Merkel cell carcinoma
Orserdu (elacestrant)	Jan 2023	Advanced or metastatic breast cancer
Jaypirca (pirtobrutinib)	Jan 2023	Relapsed or refractory mantle cell lymphoma (MCL)

FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed 01/03/2024.

Aphexda (motixafortide)

Indication	For use combination with filgrastim for mobilization of hematopoietic stem cells (HSCs) to the peripheral blood circulation to facilitate collection for subsequent autologous stem cell transplantation (ASCT) in patients with multiple myeloma (MM)
Market Landscape	• Up to 8,000 transplants performed in patients with MM; estimated 47% have difficulty with collection • Second FDA approved HSC-mobilizing agent for MM following Mozobil (plerixafor) which was approved in 2008
Clinical Studies	67.5% of patients achieved target cell collection in up to two apheresis sessions in Aphexda plus G-CSF group vs. 9.5% in placebo plus G-CSF group ($p<0.0001$)
Dosing	1.25 mg/kg SC injection following 4 days of G-CSF
Important Considerations	• Single-dose administration for most patients • Premedication for anaphylactic shock, hypersensitivity reactions, and injection site reactions • Aphexda may mobilize leukemic cells and should not be used in leukemia patients • Can cause fetal harm
Cost	$11,800 for 75 kg patient single-dose

Aphexda Prescribing Information
IPD Analytics Aphexda New Drug Review.

4
Neurology

Random Food Fact 4:

The most expensive pizza in the world costs $12,000 dollars.

Gabriel. https://www.thefactsite.com/100-random-food-facts/

Novel 2023 Neurology Approvals

Drug Name	Approval Date	Indication
Wainua (eplontersen)	Dec 2023	polyneuropathy of hereditary transthyretin-mediated amyloidosis
Agamree (vamorolone)	Oct 2023	Duchenne muscular dystrophy
Zilbrysq (zilucoplan)	Oct 2023	Generalized myasthenia gravis
Exxua (gepirone)	Sept 2023	Major depressive disorder
Zurzuvae (zuranolone)	August 2023	Postpartum depression
Rystiggo (rozanolixizumab)	June 2023	Generalized myasthenia gravis
Qalsody (tofersen)	April 2023	Amyotrophic lateral sclerosis (ALS) with SOD1 gene mutation
Daybue (trofinetide)	Mar 2023	Rett syndrome
Zavzpret (zavegepant)	Mar 2023	Migraine
Skyclarys (omaveloxolone)	Feb 2023	Friedrich's ataxia (FA)
Leqembi (lecanemab)	Jan 2023	Alzheimer's disease (AD)

FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed 1/02/2024.

Zurzuvae (zuranolone)

Indication	Postpartum depression (PPD) in adults
Market Landscape	• ~1 in 8 women in the U.S. develop PPD; ~500,000 PPD diagnoses per year • First oral FDA-approved treatment for PPD • Prior to approval, only FDA-approved treatment was Zulresso (brexanolone) which requires a lengthy infusion; SSRIs commonly used but not FDA-approved
Clinical Studies	Adult females with PPD with onset of symptoms in the third trimester or within 4 weeks of delivery saw a −4.0 (−6.3, −1.7) placebo-subtracted difference (95% CI) in the treatment group for the Hamilton Rating Scale for Depression (HAMD-17) at day 15
Dosing	Recommended dose is 50 mg by mouth daily for 14 days
Important Considerations	• Faster onset of action than current antidepressant therapies • Can be used alone or as an adjunct to oral antidepressant therapy • Boxed warning regarding hazardous activities due to CNS depressant effects • Manufacturer received complete response letter (CRL) for approval of zuranolone in MDD; FDA cited efficacy as reasoning for CRL
Cost	WAC of $15,900 for a 14-day course of therapy

Zurzuvae Prescribing Information
IPD Analytics Zurzuvae New Drug Review.

Exxua (gepirone)

Indication	Major depressive disorder (MDD) in adults
Market Landscape	• ~21 million adults in the U.S. (8.3% of all U.S. adults) had at least one depressive episode in 2021 • Numerous generic options for MDD treatment
Clinical Studies	• Mixed efficacy results across clinical trials • Approval supported by two 8-week studies in patients 18 to 69 years of age with MDD; at Week 8 in both studies, Exxua- treated patients had significant improvement in the Hamilton Depression Rating Scale (HAMD-17) total score vs. the placebo group
How Supplied	18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg extended-release tablets
Important Considerations	• First selective serotonin 1A (5-HT1A) receptor agonist approved for MDD • Similar Boxed Warning as other antidepressants regarding increased risk of suicidal thoughts; however, no warnings for weight gain or sexual dysfunction
Cost	Not yet available

Exxua Prescribing Information
IPD Analytics Exxua New Drug Review.

Agamree (vamorolone)

Indication	Duchenne muscular dystrophy (DMD)
Market Landscape	• Estimated prevalence ranges between 10,000 and 15,000 males • First-in-class dissociative steroid • Current treatment consists of exon skipping therapies and glucocorticoids
Clinical Studies	• Studied in 121 boys with DMD, 4-6 years of age, and able to ambulate • At 24 weeks, the vamorolone group had significant improvement vs. placebo in time to stand test and the 6-minute walk test
How Supplied	40 mg/mL oral suspension
Dosing	6 mg/kg orally once daily up to a maximum daily dosage of 300 mg
Important Considerations	• Inhibits the NF-κB pathway and may offer reduced side effects compared to other glucocorticoids • Warnings and precautions similar to other oral glucocorticoids
Cost	Not yet available

Agamree Prescribing Information
IPD Analytics Agamree Market and Financial Insights.

5
Diabetes/ Cardiology/ Nephrology

Random Food Fact 5:

While you likely lost count after five, academic debate rages on over how many licks it takes to get to the center of one of America's favorite Halloween candies. A machine modeled after the human tongue, developed by engineering students at Purdue University, took 364 licks.

Sanchez. https://www.thedailymeal.com/eat/weird-food-facts/

Novel 2023 Diabetes/ Cardiology/ Nephrology Approvals

Drug Name	Approval Date	Indication
Rivfloza (nedosiran)	Sept 2023	Primary hyperoxaluria type 1
Inpefa (sotagliflozin)	May 2023	Heart failure
Filspari (sparsentan)	Feb 2023	Proteinuria in adults with primary immunoglobulin A nephropathy
Jesduvroq (daprodustat)	Feb 2023	Anemia caused by chronic kidney disease (CKD) in adults on dialysis
Brenzavvy (bexagliflozin)	Jan 2023	Type 2 diabetes

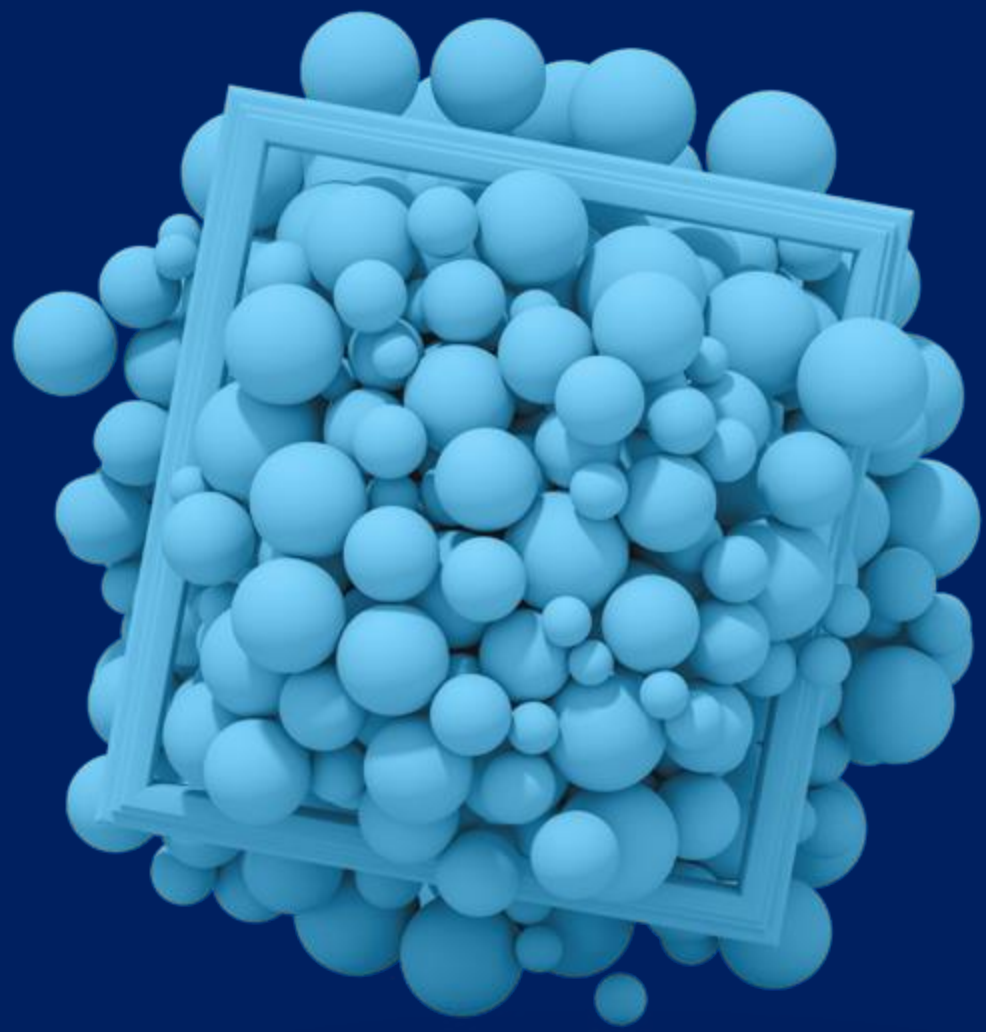
FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed 01/03/2024.

Jesduvroq (daprodustat)

Indication	Anemia caused by chronic kidney disease (CKD) in adults on dialysis
Market Landscape	• More than 500,000 patients in the U.S. receiving dialysis • Will likely compete with erythropoiesis-stimulating agents (ESAs) • Two other oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitors were expected prior to Jesduvroq but received complete response letters (CRLs)
Clinical Studies	• Jesduvroq noninferior to ESAs in both dialysis-dependent (DD) and non–dialysis-dependent (NDD) patients • Jesduvroq only approved for the DD population, due to safety concerns
How Supplied	1 mg, 2 mg, 4 mg, 6 mg, and 8 mg oral tablets
Dosing	Orally once daily
Important Considerations	• Boxed Warning for thrombotic vascular events, including major adverse cardiovascular events (MACE) • First oral treatment for anemia caused by CKD • CMS' Transitional Drug Add-on Payment Adjustment (TDAPA) implications
Cost	$31.28 per 8 mg tablet

Jesduvroq Prescribing Information.
IPD Analytics Jesduvroq New Drug Review.

6
Rare Diseases



Random Food Fact 6:

Microwaves are for popcorn, not grapes. Place a grape, almost entirely split down the middle, in a microwave, heat it and watch it flame.

Sanchez. https://www.thedailymeal.com/eat/weird-food-facts/

Novel 2023 Rare Disease Approvals

Drug Name	Approval Date	Indication
Fabhalta (iptacopan)	Dec 2023	Paroxysmal nocturnal hemoglobinuria
Pombiliti (cipaglucosidase)	Sept 2023	Late-onset Pompe disease
Veopoz (pozelimab-bbfg)	Aug 2023	CD55-deficient protein-losing enteropathy (PLE)
Sohonos (palovarotene)	Aug 2023	Fibrodysplasia ossificans progressiva
Ngenla (somatrogon)	June 2023	Growth failure due to inadequate secretion of endogenous growth hormone
Elfabrio (pegunigalsidase alfa)	May 2023	Fabry disease (FD)
Joenja (leniolisib)	Mar 2023	Activated phosphoinositide 3-kinase delta syndrome
Lamzede (velmanase alfa)	Feb 2023	Non-central nervous system manifestations of alpha-mannosidosis

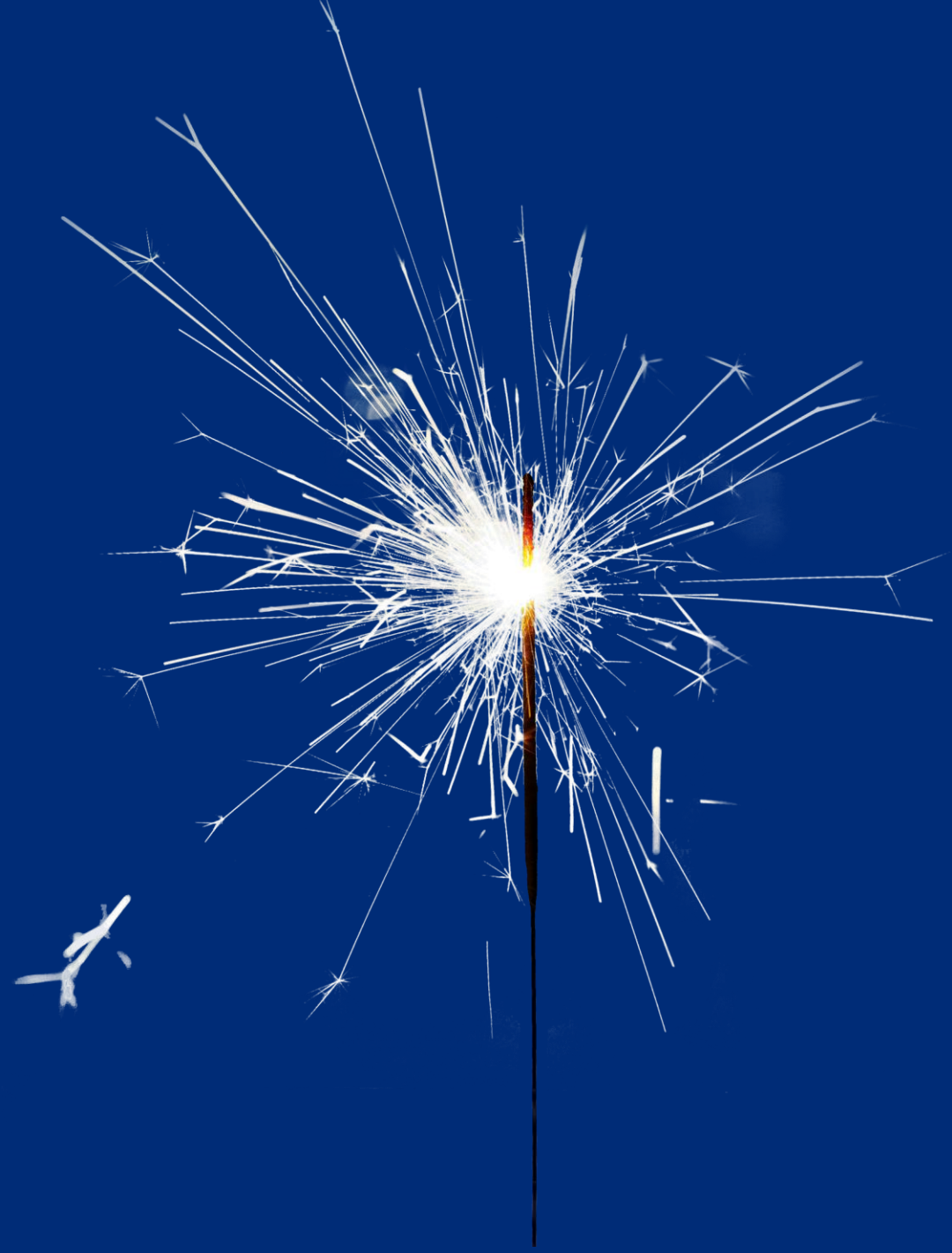
FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed 01/03/2024.

Pombiliti (cipaglucosidase)

Indication	In combination with Opfolda (miglustat) for adults with late-onset Pompe disease (LOPD) who are not improving on their current enzyme replacement therapy (ERT)
Market Landscape	• Pompe disease is a rare lysosomal storage disorder that causes deficiency of the enzyme acid alpha-glucosidase (GAA) • Can present as infantile-onset Pompe disease (IOPD) or LOPD • Now 3 FDA-approved treatments for Pompe disease, including two ERTs: Lumizyme (alglucosidase alfa) and Nexviazyme (avalglucosidase alfa)
Clinical Studies	• ERT-experienced and -naïve patients were randomized to receive Pombiliti and Opfolda or alglucosidase alfa; results showed no statistically significant difference in the primary outcome: mean change in 6-minute walk distance • Significant difference was found in a secondary outcome measure of percent predicted forced vital capacity
Dosing	20 mg/kg every other week as an IV infusion over ~ 4 hours
Important Considerations	Pombiliti, an IV ERT, and Opfolda, an oral enzyme stabilizer, are approved for use in combination only; the drugs are not co-packaged and must be sourced separately
Cost	Annual WAC cost for a 76 kg patient: Pombiliti: $671,831; Opfolda: $3,380

Pombiliti Prescribing Information
IPD Analytics Pombiliti New Drug Review.

7
Infectious Disease



Random Food Fact 7:

In 1885, while working as a pharmacist in Waco, Texas, Charles Alderton created a new drink — a unique blend of flavors we know as Dr. Pepper.

Sanchez. https://www.thedailymeal.com/eat/weird-food-facts/

Novel 2023 Infectious Disease Approvals

Drug Name	Approval Date	Indication
Defencath (taurolidine, heparin)	Nov 2023	To reduce catheter-related bloodstream infections in adults receiving hemodialysis through a central venous catheter
Beyfortus (nirsevimab)	July 2023	Prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD)
Paxlovid (nirmatrelvir, ritonavir)	May 2023	COVID-19
Xacduro (sulbactam, durlobactam)	May 2023	Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by Acinetobacter baumannii-calcoaceticus complex
Rezzayo (rezafungin)	Mar 2023	Candidemia and invasive candidiasis

FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed 0103/2024.

Beyfortus (nirsevimab)

Indication	Prevention of RSV LRTD in newborns and infants their first RSV season and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season
Market Landscape	• 1% to 3% of children < 12 months of age are hospitalized each year due to RSV • Synagis (palivizumab) previously only FDA-approved product for prevention of RSV in infants • Prenatal vaccine, Abrysvo now also approved
Clinical Studies	Statistically significant reduction in incidence of medically attended lower respiratory tract infection (LRTI) in Beyfortus group (1.2%) vs. placebo group (5.0%) in healthy late, preterm, and term infants (35 weeks or more) during their first RSV season
Dosing	Single IM injection during or prior to the RSV season
Important Considerations	• CDC Advisory Committee unanimously voted to include Beyfortus in the Vaccines for Children (VFC) program • In contrast to Synagis, approval of Beyfortus was in a broader patient population, including healthy term infants • Infant should not receive Beyfortus if pregnant mother received Abrysvo
Cost	$495 per IM injection

Beyfortus Prescribing Information
IPD Analytics Beyfortus New Drug Review.

8 Immunomodulators

Random Food Fact 8:

Indiana produces more than 20% of the United States' popcorn supply.

Blee. https://spoonuniversity.com/lifestyle/51-state-food-facts

Novel 2023 Immunomodulator Approvals

Drug Name	Approval Date	Indication
Omvoh (mirikizumab)	Oct 2023	Ulcerative colitis
Bimzelx (bimekizumab)	Oct 2023	Plaque psoriasis
Velsipity (etrasimod)	Oct 2023	Ulcerative colitis

FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed 01/03/2024.

Bimzelx (bimekizumab)

Indication	Moderate to severe plaque psoriasis in adults
Market Landscape	• 7.5 million people in the U.S. have psoriasis • Crowded treatment landscape including topical therapies, phototherapy, conventional oral agents, and targeted immunomodulators
Clinical Studies	• Bimzelx demonstrated superior rates of complete skin clearance in head-to-head trials with Cosentyx, Stelara, and Humira • 59% to 68% of patients treated with Bimzelx reached PASI 100 by Week 16
How Supplied	160 mg/mL in a single-dose prefilled syringe or single-dose prefilled autoinjector
Dosing	320 mg (two 160 mg injections) by SC injection every 8 weeks
Important Considerations	• Dual inhibition of IL-17A and IL-17F • May be dosed once every 8 weeks during maintenance therapy for most patients • Liver monitoring and warnings related to suicidal ideation
Cost	$7,200/syringe, resulting in an annual therapy cost of $93,600

Bimzelx Prescribing Information
IPD Analytics Bimzelx Market and Financial Insights.

9
Other Conditions

Random Food Fact 9:

M&M's plain chocolate candies were introduced to the U.S. in 1941 and soon became the decade's most popular Halloween candy. By 1950, several imitation products flooded the candy-coated chocolate market. M&M's solution — stamp a black "m" onto each candy.

Sanchez. https://www.thedailymeal.com/eat/weird-food-facts/

Novel 2023 Other Approvals

Drug Name	Approval Date	Indication
Filsuvez (birch triterpenes)	Dec 2023	Wounds associated with dystrophic and junctional epidermolysis bullosa
Izervay (avacincaptad pegol)	August 2023	Geographic atrophy secondary to age-related macular degeneration
Xdemvy (lotilaner)	July 2023	Demodex blepharitis
Litfulo (ritlecitinib)	June 2023	Severely patchy hair loss
Miebo (perfluorhexyloctane)	May 2023	Signs and symptoms of dry eye disease (DED)
Veozah (fezolinetant)	May 2023	Hot flashes caused by menopause

FDA. Novel Drug Approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed01/03/2024.

10
Biosimilars

Random Food Fact 10:

Kansas once outlawed serving ice cream on cherry pie.

Simon. https://www.usatoday.com/list/news/nation-now/weirdest-laws-every-state.

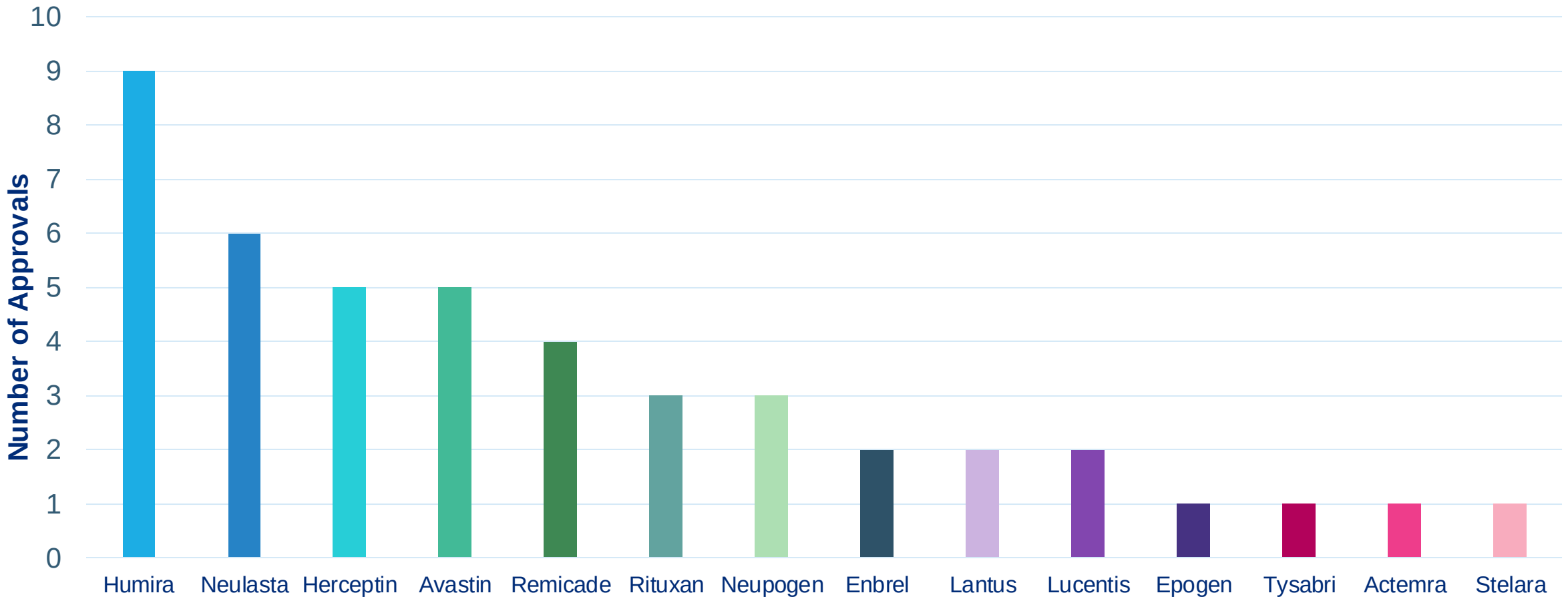
Biosimilar Approvals in 2023

Drug Name	Approval Date	Reference Product
Avzivi (bevacizumab-tnjn)	Dec 2023	Avastin (bevacizumab)
Wezlana (ustekinumab-auub)	Oct 2023	Stelara (ustekinumab)
Tofidence (tocilizumab-bavi)	Sept 2023	Actemra (tocilizumab)
Tyruko (natalizumab-sztn)	Aug 2023	Tysabri (natalizumab)
Yuflyma (adalimumab-aaty)	May 2023	Humira (adalimumab)

FDA. FDA-Approved Biosimilar Products. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed 07/11/2023.

Biosimilar Approvals

FDA has approved a total of 44 biosimilar products for 14 different reference products since 2015



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Conclusions

55

novel FDA drug approvals in 2023

7

gene and cell therapy approvals in 2023 with an acceleration in approvals in recent years

Oncology

continues to grow at a rapid pace with the most novel approvals in 2023

Neurology and Infectious Disease

approvals saw innovative therapies in 2023

Learning Assessment Questions

True or False?

(exagamglogene autotemcel) is indicated for Hemophilia A.

Which of the following are important considerations for Zurzuvae (zuranolone)?

1. Faster onset of action compared to traditional antidepressant therapy
2. Use alone or as an adjunct to oral antidepressant therapy
3. Boxed warning regarding hazardous activities due to CNS depressant effects
4. All of the above

True or False?

Beyfortus (nirsevimab) should not be given if the pregnant patient received Abrysvo more than 2 weeks prior to Beyfortus administration.

Questions

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Abbreviations

5-HT1A	Selective serotonin 1A
AAV	Adeno-associated virus
ABR	Annualized bleed rate
AD	Alzheimer's disease
ALS	Amyotrophic lateral sclerosis
ASCT	Autologous stem cell transplant
CAR-T	Chimeric antigen receptor T-cell
CI	Confidence interval
CKD	Chronic kidney disease
CMS	Centers for Medicare & Medicaid Services
CNS	Central nervous system
COVD-19	Coronavirus disease
CRL	Complete response letter
DD	Dialysis-dependent
DED	Dry eye disease
DMD	Duchenne muscular dystrophy
DLBCL	Diffuse large B-cell lymphoma
ERT	Enzyme replacement therapy
ESA	Erythropoiesis-stimulating agents
FA	Friedrich's ataxia
FD	Fabry disease
FDA	Food and Drug Administration
GAA	Acid-alpha glucosidase
G-CSF	Granulocyte colony stimulating factor
HAMD-17	Hamilton Rating Scale for Depression
HIF-PH	Hypoxia-inducible factor prolyl hydroxylase
HIV	Human Immunodeficiency Virus
HSC	Hematopoietic stem cells
ICER	Institute for Clinical and Economic Review
IL-17	Interleukin-17
IOPD	Infantile-onset Pompe disease
IV	Intravenous
LOPD	Late-onset Pompe disease
LRTD	Lower respiratory tract disease
LRTI	Lower respiratory tract infection
M	Meter
MACE	Major adverse cardiovascular events
MCL	Mantle cell lymphoma
MDD	Major depressive disorder
Min	Minute
mL	Milliliter
MM	Multiple myeloma
NDD	Non-dialysis dependent
NF-κB	Nuclear factor kappa-light-chain enhancer of activated B cells
PASI	Psoriasis area and severity index
PLE	Protein-losing enteropathy
PPD	Post-partum depression
RSV	Respiratory syncytial virus
SC	Subcutaneous
SCD	Sickle cell disease
SOD1	Superoxide dismutase 1
SNRI	Serotonin-norepinephrine reuptake inhibitors
SSRI	Selective serotonin reuptake inhibitors
TDAPA	Transitional Drug Add-on Payment Adjustment
VFC	Vaccines for Children
VOC	Vaso-occlusive crisis
VOE	Vaso-occlusive episode
WAC	Wholesale acquisition cost

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