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New Drug Update February 2023

American Drug Utilization Review Society

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Phoenix, Arizona

Our Discussion Today

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1. Overview of FDA New Drug Approval Patterns
2. CAR-T and Gene Therapy Products
3. Oncology
4. Immunomodulators
5. Neurology
6. Diabetes/Cardiology
7. Rare Diseases
8. Other
9. Biosimilars

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:

- **List** notable therapies approved by the FDA within the last year and their indications for use.
- **Describe** important considerations for therapies approved by the FDA within the last year regarding patient selection, dose, and administration.
- **Identify** novel therapies with limited therapeutic alternatives.

Learning Assessment Questions

True or False?

Skysona (elivaldogene autotemcel) is indicated for Hemophilia B.

Which of the following are important considerations for Hemgenix (etranacogene dezaparvovec) regarding patient selection?

1. Liver function
2. Inhibitor presence
3. Gender
4. All of the above

True or False?

Xenpozyme (olipudase alfa) is a novel therapeutic with limited therapeutic alternatives.

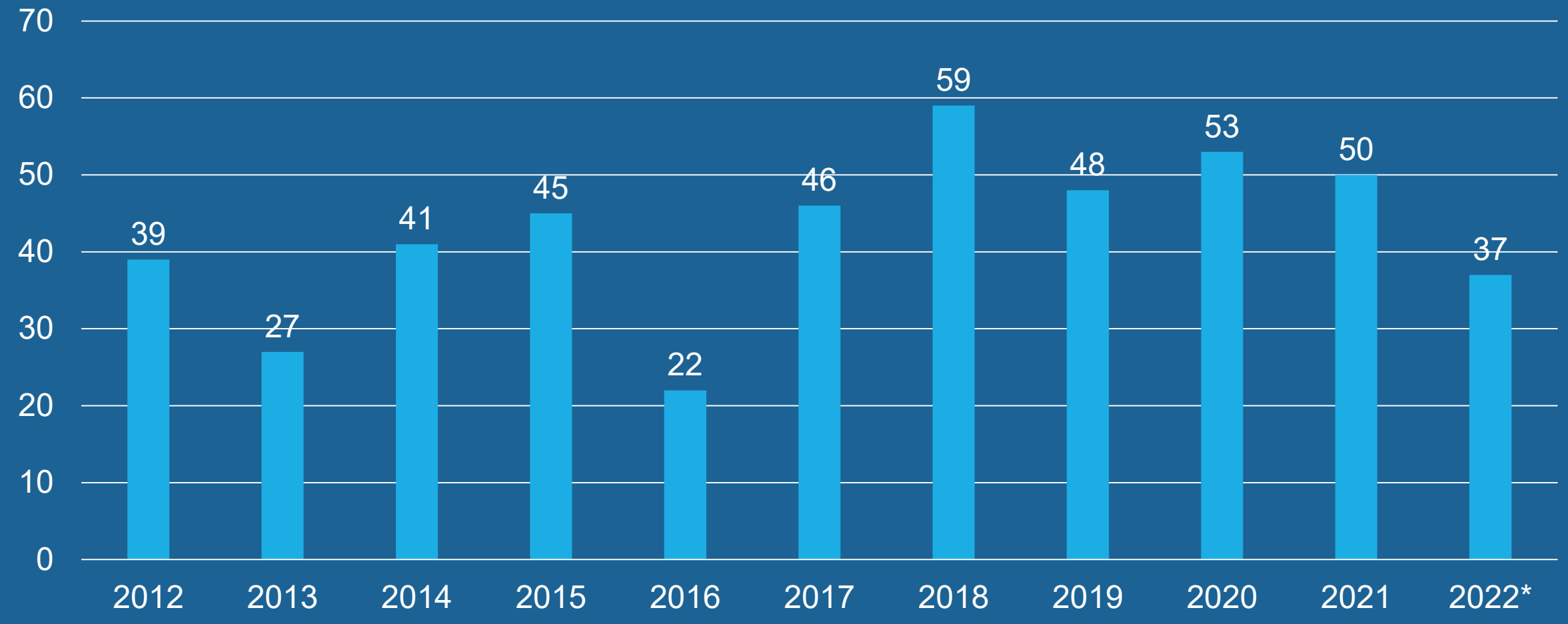
1
Overview of FDA New Drug Approval Patterns

Random State Fact 1:

Oklahoma has an official state meal consisting of the following: barbecued pork, chicken-fried steak, sausage, biscuits and gravy, fried okra, corn, squash, black-eyed peas, grits, cornbread, strawberries, and for dessert, a slice of good old-fashioned pecan pie.

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022.

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 12/29/2022.

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* As of 12/29/2022

Summary of 2021 Novel Approvals

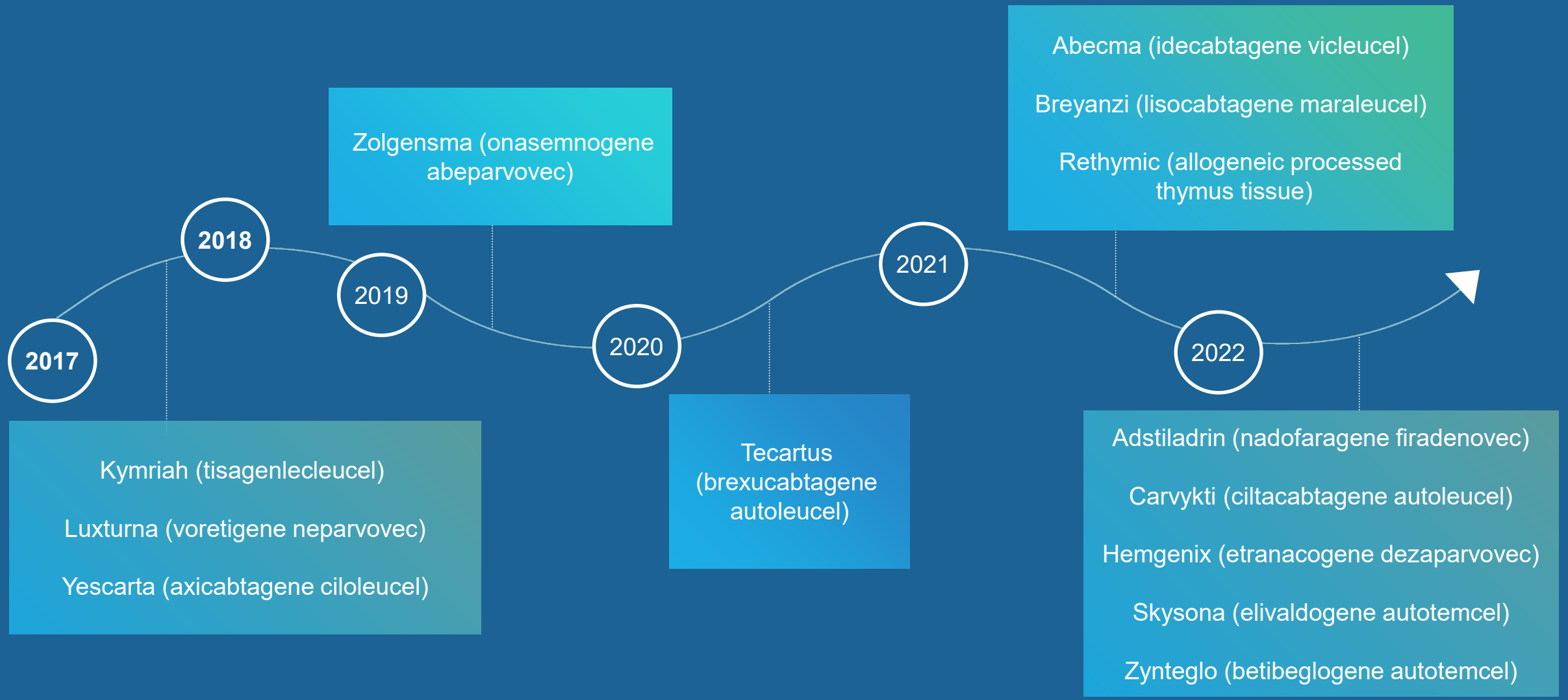
At Least One Expedited Development or Review Method: 74%

First-in-Class 54%	Orphan 52%	Fast Track 36%
Breakthrough Therapy 28%	Priority Review 68%	Accelerated Approval 28%

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 12/19/2022.

Approved CAR-T and Gene Therapy Products

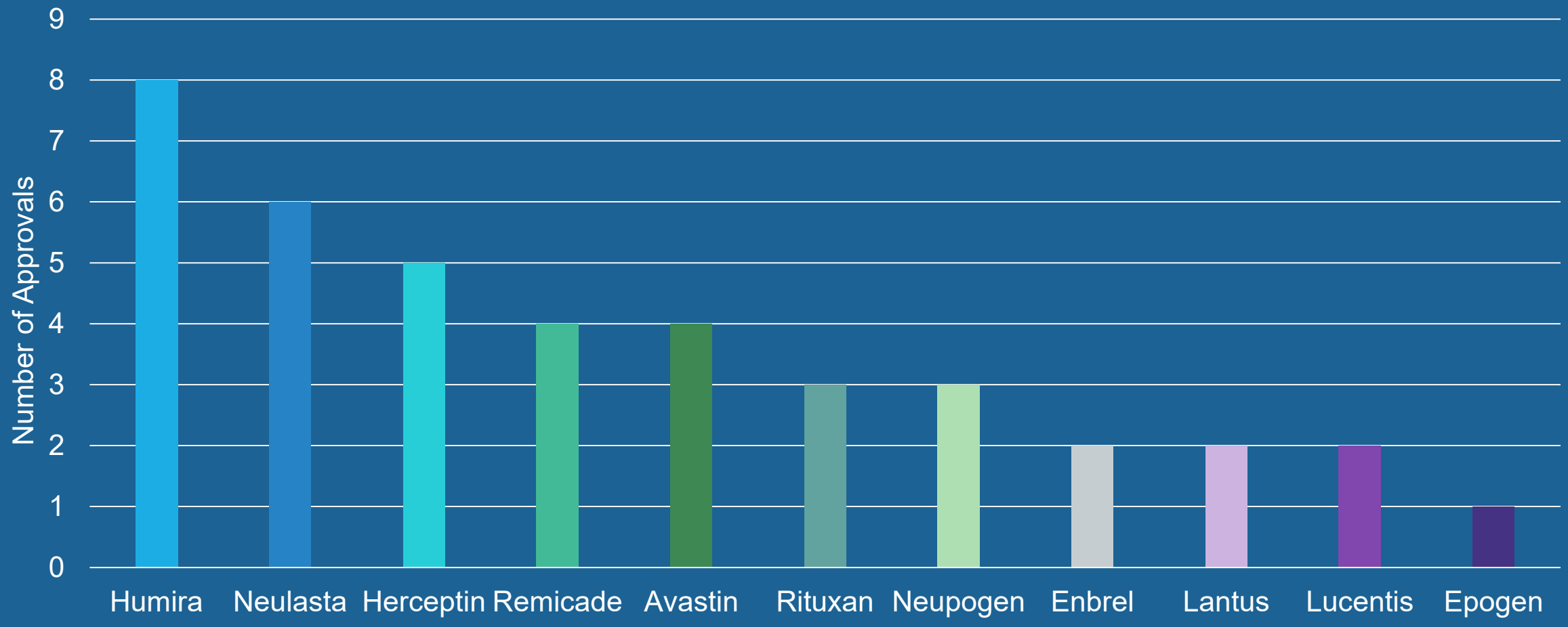
Anticipated Timeline



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 12/29/2022.
NOTE: Imlygic (talimogene laherparepvec) and Provenge (sipuleucel-T) not included on timeline

Biosimilar Approvals

FDA has approved a total of 40 biosimilar products for 11 different reference products since 2015



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 12/19/2022.
FDA. FDA-Approved Biosimilar Products. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed 12/29/2022.

2
CAR-T and Gene Therapy Products

Random State Fact 2:

Arizona is home to the only McDonald's in the world where the Golden Arches aren't golden

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022

2022 CAR-T and Gene Therapy Products

Drug Name	Approval Date	Indication
Adstiladrin (nadofaragene firadenovec)	Dec 2022	Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC)
Hemgenix (etranacogene dezaparvovec)	Nov 2022	Hemophilia B
Skysona (elivaldogene autotemcel)	Sept 2022	Cerebral adrenoleukodystrophy (CALD)
Zynteglo (betibeglogene autotemcel)	Aug 2022	Transfusion-dependent β-thalassemia (TDT)
Carvykti (ciltacabtagene autoleucel)	Feb 2022	Relapsed or refractory multiple myeloma

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 12/29/2022.

Hemgenix (etranacogene dezaparvovec)

Indication	Adult males with Hemophilia B
Market Landscape	• ~6,000 patients in U.S. with Hemophilia B (two-thirds have moderate-to-severe disease) • Regular infusions of factor IX can cost approximately $550,000 to $750,000 annually
Clinical Studies	• 54 adult men over 5 years • Annualized bleeding rate (ABR) declined 54% • 94% discontinued prophylactic factor IX
How Supplied	Weight-based; 39 different NDCs
Dosing	Single IV infusion
Important Considerations	• Baseline inhibitor testing • Baseline liver testing and follow up
Cost	$3.5 million

FDA. Hemgenix. https://www.fda.gov/vaccines-blood-biologics/vaccines/hemgenix. Accessed 12/19/2022.
IPD Analytics. Hemgenix New Drug Review.

Skysona (elivaldogene autotemcel)

Indication	Cerebral adrenoleukodystrophy (CALD)
Market Landscape	• Overall prevalence of adrenoleukodystrophy is 1 in 17,000 newborns. • Manufacturer estimates 40 patients are diagnosed with CALD in the U.S. annually • Current treatment is allogeneic HSCT
Clinical Studies	• 67 male patients up to 17 years of age • 72% likelihood of major functional disability-free survival at 24 months compared to 43% natural history progression
How Supplied	IV infusion; weight-based
Dosing	Single IV infusion; requires conditioning and hospital stay post administration
Important Considerations	• Indicated in boys 4−17 years of age • Boxed warning for hematologic malignancy
Cost	$3 million; not including hospitalization costs

FDA. Skysona. https://www.fda.gov/vaccines-blood-biologics/skysona. Accessed 12/19/2022.
IPD Analytics. Skysona New Drug Review.

Zynteglo (betibeglogene autotemcel)

Indication	Transfusion-dependent β-thalassemia (TDT)
Market Landscape	• Manufacturer estimates 1,300−1,500 individuals have TDT in the U.S., of whom 850 could be treatment eligible • Current standard of care is blood transfusions and iron chelation therapy • Reblozyl (luspatercept-aamt) is used to reduce transfusions (annual cost of $186,269 per year) • Allogeneic HSCT is potentially curative therapy for TDT
Clinical Studies	• 41 patients between 4 and 34 years • 89% (32/36) achieved transfusion independence for at least 12 months
How Supplied	IV infusion; weight-based
Dosing	Single IV infusion; requires conditioning and hospital stay post administration
Important Considerations	• Monitor for hematologic malignancies for at least 15 years post-dose • Oldest patient in the clinical trials was 34 years of age
Cost	$2.8 million; not including hospitalization costs

FDA. Zynteglo. https://www.fda.gov/vaccines-blood-biologics/zynteglo. Accessed 12/19/2022.
IPD Analytics. Zynteglo New Drug Review.

3
Oncology

Random State Fact 3:

North Carolina is home to a bald cypress tree that is "at least 2,624 years old.”

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022.

Novel 2022 Oncology Approvals

Drug Name	Approval Date	Indication
Lunsumio (mosunetuzumab)	Dec 2022	Refractory follicular lymphoma
Krazati (adagrasib)	Dec 2022	Non-small cell lung cancer
Rezlidhia (olutasidenib)	Dec 2022	Relapsed or refractory acute myeloid leukemia
Elahere (mirvetuximab soravtansine)	Nov 2022	Recurrent ovarian cancer
Tecvayli (teclistamab)	Oct 2022	Relapsed or refractory multiple myeloma
Imjudo (tremelimumab)	Oct 2022	Unresectable hepatocellular carcinoma

FDA. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 Accessed 12/29/2022.

Novel 2022 Oncology Approvals (2)

Drug Name	Approval Date	Indication
Lytgobi (futibatinib)	Sept 2022	Intrahepatic cholangiocarcinoma
Rolvedon (eflapegrastim)	Sept 2022	Reduce infections associated with febrile neutropenia
Pluvicto (lutetium (177Lu) vipivotide tetraxetan)	Mar 2022	Metastatic castration-resistant prostate cancer
Opdualag (nivolumab/ relatlimab)	Mar 2022	Unresectable or metastatic melanoma
Vonjo (pacritinib)	Feb 2022	Primary or secondary myelofibrosis
Kimmtrak (tebentafusp)	Jan 2022	Unresectable or metastatic uveal melanoma

FDA. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 Accessed 12/29/2022.

Opdualag (nivolumab/relatlimab)

Indication	Unresectable or metastatic melanoma
Market Landscape	• Melanoma accounts for about 1% of all skin cancers the U.S. • The average age at diagnosis is 65 years • Checkpoint inhibitors often used for first-line treatment [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), and Yervoy (ipilimumab)]
Clinical Studies	• Opdualag vs. Opdivo alone in 714 patients with previously untreated metastatic or unresectable melanoma • Median progression-free survival of 10.1 months with Opdualag vs. 4.6 months with Opdivo monotherapy
Dosing	480mg nivolumab and 160mg relatlimab IV every 4 weeks
Important Considerations	Increased T-cell activation compared to the activity of either antibody alone
Cost	$328,668 annually

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Opdualag Prescribing Information
IPD Analytics Opdualag New Drug Review.

Kimmtrak (tebentafusp)

Indication	Unresectable or metastatic uveal melanoma
Market Landscape	• 1500 – 2000 new cases of ocular melanoma diagnosed each year in U.S.; 85% of which are uveal • ~50% of people eventually develop metastatic disease • No FDA-approved systemic therapies in the adjuvant or metastatic settings
Clinical Studies	• Median OS 21.7 months with Kimmtrak vs.16 months with investigator's choice • Progression-free survival 3.3 months with Kimmtrak vs. 2.9 months with investigator's choice
Dosing	Intravenous: weekly following initial dosing
Important Considerations	• Boxed warning for cytokine release syndrome (CRS) • First drug of its class, as a T-cell receptor (TCR) therapeutic
Cost	Median duration of treatment of 5.3 months: average cost of $430,000 (based on median duration of treatment)

Kimmtrak Prescribing Information
IPD Analytics Kimmtrak New Drug Review.

4
Immunomodulators

Random State Fact 4: According to Insider, Columbus, Ohio is the preferred testing ground for fast-food restaurants looking to try out new products.

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022.

Novel 2022 Immunomodulator Approvals

Drug Name	Approval Date	Indication
Sotyktu (deucravacitinib)	Sept 2022	Moderate-to-severe plaque psoriasis
Spevigo (spesolimab)	Sept 2022	Generalized pustular psoriasis flares
Cibinqo (abrocitinib)	Jan 2022	Refractory, moderate-to-severe atopic dermatitis

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FDA. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022. Accessed 12/19/2022.

Cibinqo (abrocitinib)

Indication	Refractory, moderate-to-severe atopic dermatitis (AD)
Market Landscape	• 7.3% of adults and 12% of children have AD with up to 33% having moderate-to severe • Topical treatment is first-line; other options include photodynamic therapy, oral immunomodulators (e.g. cyclosporine, azathioprine), or a biologic [e.g., Adbry (tralokinumab) or Dupixent (dupilumab)] • For use after failure of at least 1 biologic
Clinical Studies	Demonstrated superior efficacy compared to Dupixent (dupilumab) in one study
How Supplied	50mg, 100mg, and 200mg oral tablets
Dosing	200mg oral once daily
Important Considerations	Same Boxed Warnings regarding serious infections, mortality, malignancies, major adverse cardiovascular events, and thromboses as other JAK inhibitors
Cost	$59,787 annually

Cibinqo Prescribing Information
IPD Analytics. Cibinqo New Drug Review.

Sotyktu (deucravacitinib)

Indication	Moderate-to-severe plaque psoriasis (PsO)
Market Landscape	Second oral targeted immunomodulator on the market [Otezla (apremilast) first]
Clinical Studies	Sotyktu demonstrated superior efficacy to Otezla at 16, 24, and 52 weeks in two separate studies
How Supplied	6mg tablets
Dosing	6mg oral once daily
Important Considerations	FDA did not require Boxed Warnings or a second-line indication for Sotyktu despite its relationship to JAK inhibitors
Cost	$75,000 annually

Sotyktu Prescribing Information
IPD Analytics. Sotyktu New Drug Review.

5
Neurology

Random State Fact 5: Have you ever carved a jack-o'-lantern and stopped to think, "I could ride this gourd across the sea in a race to glorious victory?" Well, does Oregon have the event for you: the West Coast Giant Pumpkin Regatta

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022.

Novel 2022 Neurology Approvals

Drug Name	Approval Date	Indication
Briumvi (ublituximab)	Dec 2022	Relapsing forms of multiple sclerosis
Relyvrio (sodium phenylbutyrate/taurursodiol)	Sept 2022	Amyotrophic lateral sclerosis (ALS)
Amvuttra (vutrisiran)	Jun 2022	Polyneuropathy of hereditary transthyretin-mediated amyloidosis
Ztalmy (ganaxolone)	Mar 2022	Seizures in cyclin-dependent kinase-like 5 deficiency disorder

FDA. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022. Accessed 12/19/2022.

Relyvrio (sodium phenylbutyrate/taurursodiol)

Indication	ALS
Market Landscape	• 24,800 people are living with ALS in the United States • Third FDA-approved therapy for ALS [riluzole and Radicava (edaravone)] • Relyvrio may be used as monotherapy with existing therapies
Clinical Studies	• 137 adults; after 24 weeks Relyvrio group scored 2.32 points higher on the Revised ALS Functional Rating Scale (ALSFRS-R) total score than the placebo group • Median survival Relyvrio 23.5 months vs. placebo 18.7 months
How Supplied	Packet for suspension (3g sodium phenylbutyrate and 1g taurursodiol)
Dosing	1 packet administered twice daily following initial dosing
Important Considerations	• Likely to be used as add-on to current treatments • ICER cost-effectiveness threshold $9,100 – $30,700 per year
Cost	WAC of $158,313 for the first year of treatment

Relyvrio Prescribing Information
IPD Analytics Relyvrio New Drug Review.
ICER. https://icer.org/news-insights/press-releases/icer-publishes-final-evidence-report-and-policy-recommendations-on-treatments-foramyotrophic-lateral-sclerosis/. Accessed 01/05/2023.

6
Diabetes/ Cardiology

Random State Fact 6: According to NPR, there are a grand total of two escalators in Wyoming.

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022.

Novel 2022 Diabetes/Cardiology Approvals

Drug Name	Approval Date	Indication
Tzield (teplizumab)	Nov 2022	Delay the onset of stage 3 type 1 diabetes (T1D)
Mounjaro (tirzepatide)	May 2022	To improve blood sugar control in diabetes, in addition to diet and exercise
Camzyos (mavacamten)	Apr 2022	Certain classes of obstructive hypertrophic cardiomyopathy

FDA. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 Accessed 12/19/2022.

Tzield (teplizumab-mzwv)

Indication	Delay the onset of stage 3 T1D
Market Landscape	• 5%–10% of people with diabetes have T1D • Manufacturer will focus on the 30,000 eligible patients with direct relatives affected with T1D • No other novel agents in late-stage development for the delay of T1D
Clinical Studies	• 76 patients over a median follow-up of 51 months: • 45% with Tzield progressed to stage 3 T1D vs. 72% with placebo • Time from randomization to diagnosis of stage 3 T1D was 50 months for Tzield vs. 25 months for placebo
Dosing	BSA based dose; IV infusion once daily for 14 consecutive days
Important Considerations	• Confirm Stage 2 type 1 diabetes • Ensure the clinical history of the patient does not suggest type 2 diabetes
Cost	$193,900 per 14-day course of treatment at one vial per dose

Mounjaro (tirzepatide)

Indication	Improve blood sugar control in adults with type 2 diabetes (T2D)
Market Landscape	• Will likely compete with other GLP-1 agonists [e.g., Trulicity (dulaglutide) and Ozempic (semaglutide)] • Novel dual mechanism of action
Clinical Studies	• A1c reduction % of 2.01–2.30 vs.1.86 with Ozempic (semaglutide) • Participants treated with Mounjaro lost between 12 pounds and 25 pounds on average
How Supplied	2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, or 15mg per 0.5mL in single-dose pen
Dosing	5mg, 10mg, and 15mg SC once weekly
Important Considerations	• Boxed warning for thyroid C-cell tumors • Manufacturer pursuing a weight loss indication • Cardiovascular data due in 2024
Cost	$12,666 per year

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Mounjaro Prescribing Information
IPD Analytics Mounjaro New Drug Review.

7
Rare Diseases

Random State Fact 7: Rhode Island is home to a roadside attraction known as the Big Blue Bug, and folks, it's exactly what you think it is. Built in 1980 as a way to advertise New England Pest Control, this massive termite became so iconic that in 2012, the company changed its name to Big Blue Bug Solutions.

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022.

Novel 2022 Rare Disease Approvals

Drug Name	Approval Date	Indication
Xenpozyme (olipudase alfa)	Aug 2022	Acid Sphingomyelinase Deficiency (ASMD)
Pyrukynd (mitapivat)	Feb 2022	Hemolytic anemia in pyruvate kinase deficiency
Enjaymo (sutimlimab-jome)	Feb 2022	Decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease

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FDA. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 Accessed 12/19/2022.

Xenpozyme (olipudase alfa)

Indication	ASMD
Market Landscape	• Fewer than 120 patients with ASMD in the U.S.; of which two-thirds are pediatric patients • Only available treatments for ASMD prior to Xenpozyme were supportive therapies that address specific symptoms
Clinical Studies	Statistically significant improved lung function, platelet count, and reduced spleen and liver volumes compared to placebo
How Supplied	Single-dose vial
Dosing	IV every 2 weeks; weight-based
Important Considerations	• First disease-specific therapy • Boxed warning for anaphylaxis
Cost	$750,000 to $1,800,000 annual cost based on average weights in trials

8
Other

Random State Fact 8: Spearfish, South Dakota holds the world record for the fastest temperature change: On January 22, 1943, the temperature changed from -4 degrees Fahrenheit to 45 degrees within the span of two minutes.

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022

Novel 2022 Other Approvals

Drug Name	Approval Date	Indication
NexoBrid (anacaulase)	Dec 2022	Eschar in adults with thermal burns
Xenoview (hyperpolarized Xe-129)	Dec 2022	To evaluate pulmonary function and imaging
Sunlenca (lenacapavir)	Dec 2022	HIV infections that cannot be treated with other available treatments
Rebyota (fecal microbiota, live)	Nov 2022	Recurrent Clostridioides difficile infection (CDI)
Omlonti (oomidenepag isopropyl)	Sept 2022	Open-angle glaucoma or ocular hypertension
Terlivaz (terlipressin)	Sept 2022	Hepatorenal syndrome (HRS)
Vtama (tapinarof)	May 2022	PsO
Voquezna (vonoprazan, amoxicillin, and clarithromycin)	May 2022	Helicobacter pylori infection
Vivjoa (oteseconazole)	Apr 2022	Recurrent vulvovaginal candidiasis (RVVC)
Vabysmo (faricimab)	Jan 2022	Neovascular (wet) aged-related macular degeneration and diabetic macular edema

FDA. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 Accessed 12/29/2022

Rebyota (fecal microbiota, live-jslm)

Indication	Recurrent CDI
Market Landscape	• 500,000 patients with CDI in the U.S. each year; 15% to 30% experience reoccurrence with 40% of those experiencing a 2nd recurrence • Guidelines suggest Zinplava (bezlotoxumab) for 1st recurrence of CDI • Fecal microbiota transplantation (FMT) is recommended in patients experiencing 2 or more recurrences of CDI
Clinical Studies	• 262 adults with ≥ 1 CDI recurrences • Absence of CDI diarrhea 8 weeks after treatment: 70.6% with Rebyota vs. 57.5% with placebo • >90% remained free of CDI through 6 months
How Supplied	150mL single-dose rectal suspension
Dosing	Single-rectal administration 24 to 72 hours after the last dose of antibiotics
Important Considerations	• 1st FDA approved microbiome therapy • Manufactured from human fecal matter
Cost	$9,000 per dose

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Rebyota Prescribing Information
IPD Analytics. Rebyota Payer Update.

Vtama (tapinarof)

Indication	Mild, moderate, or severe PsO
Market Landscape	• Crowded market with numerous topical and systemic options • Fewer associated limitations may increase uptake
Clinical Studies	Treatment success of 35.4% vs. 6.0% (vehicle cream) and 40.2% vs. 6.3% (vehicle cream) in two trials
How Supplied	1% cream in 60 gram tube
Dosing	Apply to affected areas once daily
Important Considerations	• 1st FDA-approved aryl hydrocarbon receptor (AhR) agonist • Does not have limitations with regard to treatment duration or application areas
Cost	$1,325 per tube

Vivjoa (oteseconazole)

Indication	Females with a history of RVVC who are NOT of reproductive potential
Market Landscape	• RVVC defined as ≥3 symptomatic acute episodes of VVC in 12 months • Affects approximately 138 million women worldwide each year • Oral fluconazole is current standard of care
Clinical Studies	No recurrence in the 48-week maintenance period for 93.3% and 96.1% of women treated with Vivjoa vs. 57.2% and 60.6% with placebo
How Supplied	150mg oral capsule
Dosing	600mg day 1, 450mg day 2, 150mg once weekly for 11 weeks
Important Considerations	• First FDA-approved medication for the treatment of RVVC • For females who are NOT of reproductive potential
Cost	~$3,000 for complete 12 week course

Vivjoa Prescribing Information
IPD Analytics. Vivjoa New Drug Review.

9
Biosimilars

Random State Fact 9: The official state snack of Utah is Jell-O, and according to Thrillest, residents eat more of the jiggly stuff per capita than anywhere else in the USA.

Colussi. https://www.buzzfeed.com/marycolussi/fascinating-us-state-facts Accessed 12/19/2022

Biosimilar Approvals in 2022

Drug Name	Approval Date	Reference Product
Idacio (adalimumab-aacf) Injection	Dec 2022	Humira
Releuko (filgrastim-ayow) Injection	Feb 2022	Neupogen
Fylnetra (pegfilgrastim-pbbk) Injection	May 2022	Neulasta
Stimufend (pegfilgrastim-fpgk) Injection	Sept 2022	Neulasta
Vegzelma (bevacizumab-adcd) Injection	Sept 2022	Avastin
Alymsys (bevacizumab-maly) Injection	April 2022	Avastin
Cimerli (ranibizumab-eqrn) Intravitreal Injection	Aug 2022	Lucentis

FDA. FDA-Approved Biosimilar Products. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed 12/29/2022.

Conclusions

37

Novel FDA drug approvals in 2022

5

Gene and CAR-T therapy approvals

Oncology

continues to grow at a rapid pace with the most novel approvals in 2022

Gene therapy

approvals are accelerating

Continuing increase in

Specialty therapy

approvals including those for rare diseases

Learning Assessment Questions

True or False?

Skysona (elivaldogene autotemcel) is indicated for Hemophilia B

Which of the following are important considerations for Hemgenix (etranacogene dezaparvovec) regarding patient selection?

1. Liver function
2. Inhibitor presence
3. Gender
4. All of the above

True or False?

Xenpozyme (olipudase alfa) is a novel therapeutic with limited therapeutic alternatives

Questions

Bethany Holderread, Pharm.D.

For more detailed information about this topic, MercerRx Government or to view the demo of MercerRx Passage, visit our website @ www.mercer.com/mercerrx-government.html

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Abbreviations

ABR	Annualized bleeding rate
AD	Atopic dermatitis
ALS	Amyotrophic lateral sclerosis
AhR	Aryl hydrocarbon receptor
ALSFRS-R	ALS Functional Rating Scale
BCG	Bacillus Calmette-Guérin
BSA	Body surface area
CALD	Cerebral adrenoleukodystrophy
CAR-T	Chimeric antigen receptor T-cell
CDI	Clostridioides difficile infection
CIS	Carcinoma in situ
CRS	Cytokine release syndrome
FDA	United States Food and Drug Administration
FMT	Fecal microbiota transplantation
GLP-1	Glucagon-like peptide 1
HRS	Hepatorenal syndrome
HSCT	Hematopoietic stem cell transplantation
ICER	Institute for Clinical and Economic Review
IV	Intravenous
JAK	Janus kinase
NDC	National drug code
NMIBC	Non-muscle-invasive bladder cancer
OS	Overall survival
PsO	Plaque psoriasis
RVVC	Recurrent vulvovaginal candidiasis
SC	Subcutaneous
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TCR	T-cell receptor
TDT	Transfusion-dependent β-thalassemia
VVC	Vulvovaginal candidiasis

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A business of Marsh McLennan