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Pharmaceutical Innovations & Novel Drug Approvals with Implication on Health System Practice

Presenter:

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Pharmaceutical Innovations & Novel Drug Approvals with Implication on Health System Practice

A presentation for HealthTrust Members

April 2, 2026

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Conflict of Interest Disclosure

- Tim Krafcisin, Cristina Alberti and John Maneno do not have any financial conflicts of interest to report
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Objectives

Pharmacists, Nurses & Healthcare Executives:

1. Recognize novel therapies that are FDA-approved or in the pharmaceutical pipeline that may have implications on health system practice
2. Identify key therapeutic classes of innovation in the U.S. market for 2026 and beyond
3. Recall novel GLP-1 indications, formulations and dosing frequencies for use and barriers to success within the growing biosimilar landscape

Pharmacy Technicians:

1. Identify the mechanism of action of GLP-1 receptor agonists and the resulting cardiovascular/endocrine benefits and adverse events this class of medications has on patients
2. Recall the dosage forms and frequency of administration of novel HIV preexposure prophylaxis medications
3. Recognize biosimilar interchangeability and how it may improve patient access to costly injectable drugs

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GLP-1 Receptor Agonists

GLP-1 Agonist Overview

- Growing medication class that has had significant implications on non-acute classes of trade
- Robustly improved cardiovascular/endocrine patient outcomes via:
  - Stimulation of glucose-dependent insulin release from the pancreas
  - Inhibition of post-meal glucagon release
  - Reduction in gastric emptying
- Approved uses include T2DM, obesity, MACE, OSA, eGFR decline, ESRD, CV death, MASH
  - DM incidence is currently 830 million people worldwide, with increasing trajectory
  - U.S. obesity prevalence increased from 30% in 2000 to 40% in 2023

Current GLP-1 Agonist Landscape

Brand Name	Generic Name	Manufacturer	Route	Frequency	Indication(s)	Approval Year	2026 Revenue Estimate ($)
Wegovy Pill Wegovy	Semaglutide	Novo Nordisk	Oral SC	Daily Once weekly	Obesity, MACE, MASH (SC only)	2025 2021	10.3B 0.603B
Ozempic	Semaglutide	Novo Nordisk	SC	Once weekly	T2D, MACE, eGFR decline, ESRD, CV death	2017	13.5B
Rybelsus Ozempic	Semaglutide	Novo Nordisk	Oral	Daily	T2D, MACE	2020	1.2B
Mounjaro	Tirzepatide	Eli Lilly	SC	Once weekly	T2D	2022	15.4B
Zepbound	Tirzepatide	Eli Lilly	SC	Once weekly	Obesity, OSA	2023	17.6B
Trulicity	Dulaglutide	Eli Lilly	SC	Once weekly	T2D, MACE	2014	2.3B
Saxenda	Liraglutide	Novo Nordisk	SC	Daily	Obesity	2014	0.018B
Victoza	Liraglutide	Novo Nordisk	SC	Daily	T2D, MACE	2010	0.052B
Bydureon	Exenatide	Astra Zeneca	SC	Once weekly	T2D	2012	DSC
Byetta	Exenatide	Astra Zeneca	SC	Twice daily	T2D	2005	DSC

CV = cardiovascular; DSC = discontinued; eGFR = estimated glomerular filtration rate; ESRD = end stage renal disease; MACE = major adverse cardiovascular events; MASH = metabolic dysfunction-associated steatohepatitis; OSA = obstructive sleep apnea; SC = subcutaneous; T2D = Type 2 diabetes mellitus

GLP-1 Growth Trends

Brand Name	Generic Name	Manufacturer	Route	Pending Indication(s)/Dose	Status
FDA Approved – Seeking Novel Indication/Dose					
Ozempic	Semaglutide	Novo Nordisk	SC	PAD	Pending
Rybelsus	Semaglutide	Novo Nordisk	Oral	25, 50 mg	Phase III
Mounjaro	Tirzepatide	Eli Lilly	SC	T2D^, MACE, T1D	Phase III
Seeking FDA Approval					
LY3502970	Orforglipron	Eli Lilly	Oral	T2D, obesity, OSA	Phase III
LY3437943	Retatrutide	Eli Lilly	SC	T2D	Phase III
CagriSema	Cagrilintide & Semaglutide	Novo Nordisk	SC	T2D	Phase III
MET-097i	TBD	Pfizer	SC	Obesity	Phase II
GSBR-1290	Aleniglipron	Structure Therapeutics	Oral	Obesity	Phase II

MACE = major adverse cardiovascular events; OSA = obstructive sleep apnea; PAD = peripheral artery disease; SC = subcutaneous; T1D = type 1 diabetes mellitus; T2D = type 2 diabetes mellitus
^Seeking approval in the pediatric population

Orforglipron – ATTAIN-1 Trial

NCT05869903	
Study Design	Multicenter, randomized, double-blind, placebo-controlled, phase 3 study
Purpose	Evaluate the safety and efficacy of once-daily orforglipron at varying doses as compared with placebo as an adjunct to healthy diet and physical activity for 72 weeks
Manufacturer	Eli Lilly
Potential Indications	• T2DM, obesity, OSA
Mechanism of Action	• GLP-1 receptor agonist
Key Inclusion Criteria	• Adults ≥18 years • BMI ≥30 or 27-29.9 kg/m^2 with at least one obesity-related complication (HTN, dyslipidemia, CVD, OSA) • ≥1 previously documented unsuccessful dietary effort to lose body weight
Key Exclusion Criteria	• Diagnosis of DM • Change in body weight (gain or loss) of ≥5 kg within 90 days before screening
Interventions	• Randomization in a 3:3:3:4 ratio to receive orally once daily: ○ Orforglipron 6 mg ○ Orforglipron 12 mg ○ Orforglipron 36 mg ○ Placebo
Key Efficacy Outcomes	• Primary ○ Percent change body weight from baseline to week 72 • Secondary ○ Category of weight reduction ○ Change in waist circumference
Key Safety Outcomes	• Adverse event incidence

BMI = body mass index; CVD = cardiovascular disease; DM = diabetes mellitus; HTN = hypertension; OSA = obstructive sleep apnea; T2DM = type 2 diabetes mellitus

Orforglipron – ATTAIN-1 Trial

NCT05869903				
Primary Efficacy Results				
	Orforglipron 6 mg (n=723)	**Orforglipron 12 mg (n=725)**	**Orforglipron 36 mg (n=730)**	**Placebo (n=949)**
Change in body weight, % (95% CI)	-7.5% (-8.2, -6.8)	-8.4% (-9.1, -7.7)	-11.2% (-12.0, -10.4)	-2.1% (-2.8, -1.4)
Difference vs placebo, % (95% CI)	**-5.5% (-6.5, -4.5)**	**-6.3% (-7.3, -5.4)**	**-9.1% (-10.1, -8.1)**	Reference
Key Secondary Efficacy Results				
≥20% weight reduction, % of patients (95% CI)	6.4% (4.6, 8.3)	9.0% (6.9, 11.1)	18.4% (15.5, 21.3)	2.8% (1.6, 4.0)
Change in waist circumference, cm (95% CI)	-7.1 (-7.7, -6.5)	-8.2 (-8.9, -7.5)	-10.0 (-10.7, -9.3)	-3.1 (-3.7, -2.4)
Key Safety Results				
Any adverse event, n (%)	603 (83.4%)	627 (86.6%)	620 (85.2%)	763 (80.5%)
Serious adverse event, n (%)	40 (5.5%)	39 (5.4%)	28 (3.8%)	46 (4.9%)
Death, n (%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
GI disorder leading to discontinuation, n (%)	25 (3.5%)	38 (5.2%)	51 (7.0%)	4 (0.4%)

GI = gastrointestinal disorder

Cagrilintide-Semaglutide – REDEFINE-2 Trial

NCT05394519	
Study Design	Multicenter, randomized, double-blind, placebo-controlled, phase 3a study
Purpose	Evaluate the safety and efficacy of once-weekly cagrilintide-semaglutide as compared with placebo as an adjunct to lifestyle interventions for weight management in overweight/obese patients or those with T2D
Manufacturer	Novo Nordisk
Potential Indications	• T2D
Mechanism of Action	• GLP-1 receptor agonist + amylin analog
Key Inclusion Criteria	• Adults ≥18 years • BMI ≥27.0 kg/m^2 • A1c between 7-10% • At least one unsuccessful dietary effort to lose weight • T2D diagnosis ≥180 days prior to screening, no glucose lowering agents received ≥90 days prior to screening
Key Exclusion Criteria	• Previous surgical or pharmacologic treatment for obesity within 90 days prior to screening
Interventions	• Randomization in a 3:1 ratio to receive: ○ Cagrilintide-semaglutide 0.25 mg once weekly (dose escalation Q4W until 2.4 mg maintenance dose reached) ○ Placebo once weekly
Key Efficacy Outcomes	• Primary ○ Percent change in body weight from baseline to week 68 ○ Percentage of patients with a reduction in body weight of ≥5% from baseline to week 68 • Secondary ○ Percentage of patients with a reduction in body weight of ≥20% from baseline to week 68 ○ Change from baseline in IWQOL-Lite-CT physical function score ○ Change from baseline in SF-36v2 physical function score
Key Safety Outcomes	• Adverse event incidence

BMI = body mass index; GLP = glucagon-like peptide; IWQOL = Impact of Weight on Quality of Life; SF = short form; T2D = Type 2 diabetes mellitus; Q4W = every 4 weeks

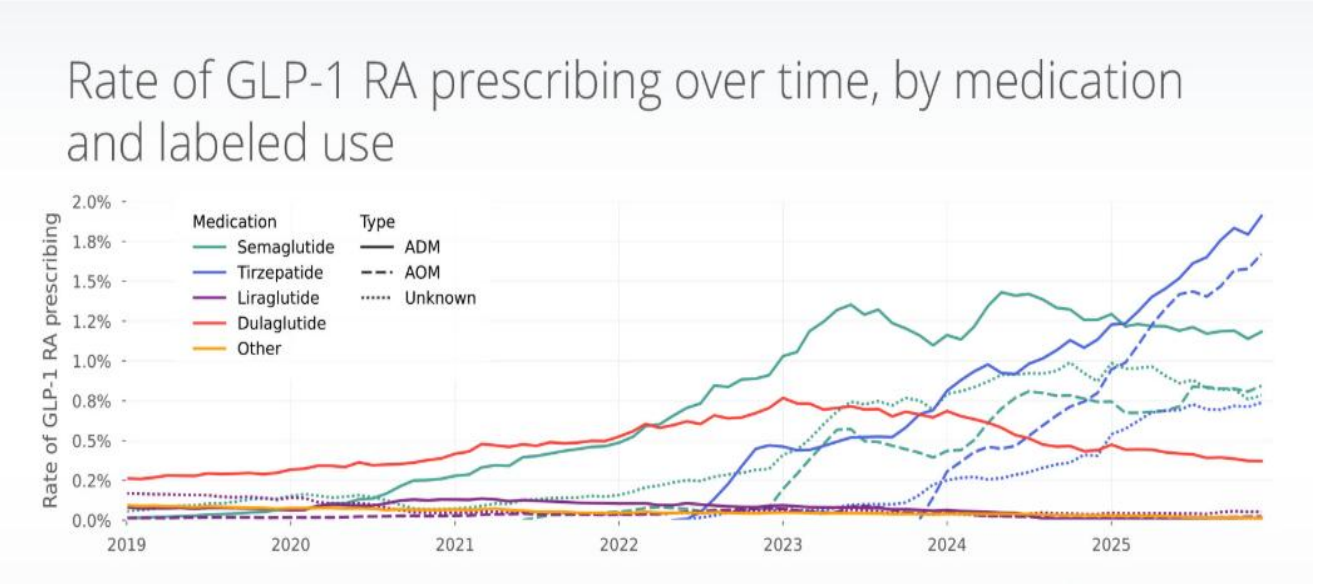
Cagrilintide-Semaglutide – REDEFINE-2 Trial

NCT05394519			
Primary Efficacy Results			
	Cagrilintide-semaglutide (n=904)	**Placebo (n=302)**	**Treatment Difference (95% CI)**
Change in body weight at week 68	**-13.7%**	**-3.4%**	**-10.4% (-11.2%, -9.5%)**
Patients with body weight reduction ≥5%, %	**83.6%**	**30.8%**	**52.8% (46.7%, 58.9%)**
Key Secondary Efficacy Results			
Patients with body weight reduction ≥20%, %	**22.9%**	**0.5%**	**22.4% (19.5%, 25.3%)**
Change from baseline in IWQOL-Lite-CT physical function score	**16.1**	**10.4**	**5.8 (3.2, 8.2)**
Change from baseline in SF-36v2 physical function score	**5.0**	**3.1**	**1.9 (0.9, 3.0)**
Key Safety Results			
Any adverse event, n (%)	815 (90.2)	258 (85.4)	---
Serious adverse event, n (%)	94 (10.4)	39 (12.9)	---
Death, n (%)	4 (0.4)	0 (0.0)	---
Clinically significant hypoglycemia, n (%)	54 (6.0)	10 (3.3)	---
GI disorder, n (%)	655 (72.5)	104 (34.4)	---
Injection-site reaction, n (%)	44 (4.9)	0 (0.0)	

CI = confidence interval; GI = gastrointestinal; IWQOL = Impact of Weight on Quality of Life; SF = short form

GLP-1 Growth Trends

- As of December 2025, GLP-1 prescriptions make up >7% of all prescriptions
- 120 metabolic assets are currently in development across 60 companies
- Mounjaro and Zepbound projected to see continued growth in 2026
- The GLP-1 global market could reach as high as $100B by the 2030s
- Oral GLP-1s are forecasted to capture ~24% or ~$22B of the global weight-loss market by 2030
- Numerous supply considerations
  - Anticipation of drug shortages
  - Supply chain evaluation



Source: Truveta Pharmaceuticals; https://www.truveta.com/blog/research/glp-1-ra-prescription-trends-december-2025/

GLP-1 Forecast

- Pricing and coverage
- Semaglutide's loss of exclusivity
  - 2031 for the U.S.
- Dual receptor therapies:
  - GIP/GLP-1 & GLP-1/amylin analog
- Triple receptor therapies:
  - GIP, GLP-1, glucagon
- Oral therapies
  - Shift from induction focus to long-term use
- Label expansions
  - Respiratory disorders
  - Curbing addiction
  - Infertility

Wegovy Subcutaneous vs Oral Supply Chain Impact	
Subcutaneous	**Oral**
2.4 mg once weekly	25 mg once daily
125 mg per patient, per year	9,125 mg per patient, per year
~2B mg globally per year*	87x more mg needed globally per year

*19M people currently prescribed GLP-1 drugs

Pharmacists, Nurses & Healthcare Executives

Assessment Question #1

Based on the FDA-approved and pipeline GLP-1 agonists discussed in this presentation, which of the following descriptions is correct?

A. Cagrilintide-semaglutide and tirzepatide are both pipeline drugs
B. Liraglutide is a pipeline drug, while retatrutide is an FDA-approved drug
C. Orforglipron is a pipeline drug, while semaglutide is an FDA-approved drug
D. Retatrutide and dulaglutide are both FDA-approved drugs

Pharmacists, Nurses & Healthcare Executives

Assessment Question #1: Correct Response

Based on the FDA-approved and pipeline GLP-1 agonists discussed in this presentation, which of the following descriptions is correct?

A. Cagrilintide-semaglutide and tirzepatide are both pipeline drugs

B. Liraglutide is a pipeline drug, while retatrutide is an FDA-approved drug

C. **Orforglipron is a pipeline drug, while semaglutide is an FDA-approved drug**

D. Retatrutide and dulaglutide are both FDA-approved drugs

Pharmacists, Nurses & Healthcare Executives

Assessment Question #2

Which of the following currently FDA-approved GLP-1 agonists is pursuing novel indications for T1DM, as well as T2DM in the pediatric population?

A. Ozempic (semaglutide)
B. Mounjaro (tirzepatide)
C. Victoza (liraglutide)
D. Trulicity (dulaglutide)

Pharmacists, Nurses & Healthcare Executives

Assessment Question #2: Correct Response

Which of the following currently FDA-approved GLP-1 agonists is pursuing novel indications for T1DM, as well as T2DM in the pediatric population?

A. Ozempic (semaglutide)
B. Mounjaro (tirzepatide)
C. Victoza (liraglutide)
D. Trulicity (dulaglutide)

Pharmacy Techs

Assessment Question #3

According to the results of the REDEFINE-2 trial, which of the following was the most frequent adverse event associated with cagrilintide-semaglutide use?

A. Clinically significant hypoglycemia
B. Injection-site reactions
C. Gastrointestinal disorders
D. Death

Pharmacy Techs

Assessment Question #3: Correct Response

According to the results of the REDEFINE-2 trial, which of the following was the most frequent adverse event associated with cagrilintide-semaglutide use?

A. Clinically significant hypoglycemia
B. Injection-site reactions
C. **Gastrointestinal disorders**
D. Death

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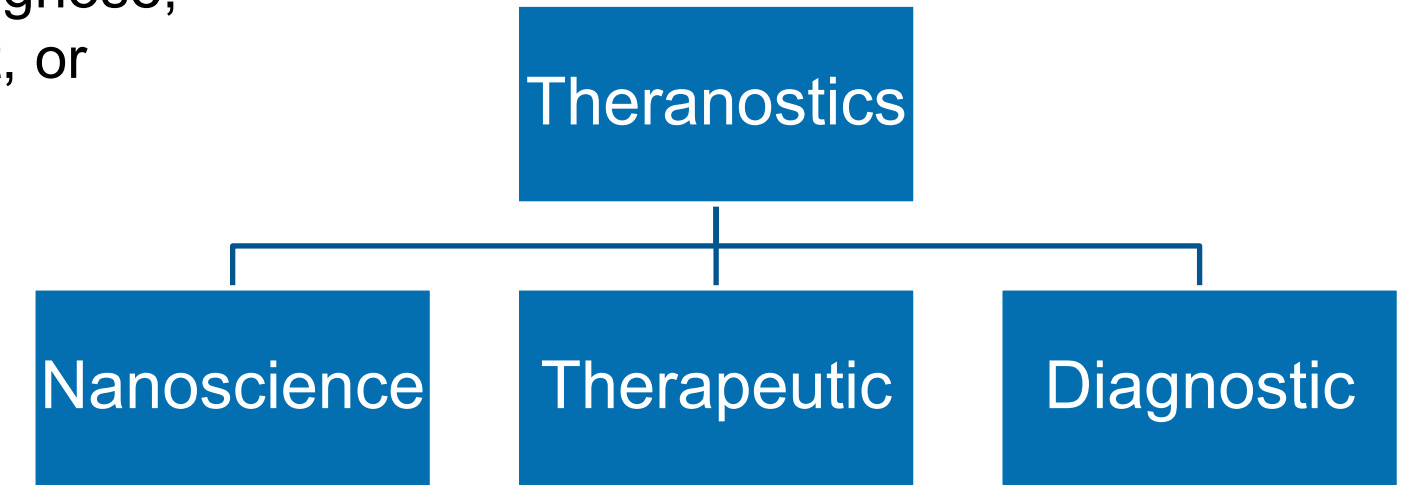
Theranostics

Theranostics

- Radiopharmaceuticals contain a radioactive substance labeled with one or more ingredients and are intended to diagnose, stage a disease, monitor treatment, or provide therapy
- Projected growth
  - 2026: $7.4B
  - 2036: $10.4B
- Currently FDA approved:
  - Diagnostic: 38
  - Therapeutic: 4
- Pipeline Phase III:
  - Diagnostic: 18
  - Therapeutic: 7



Targeted Therapeutics Over the Years

Atom Bomb Approach

- Chemotherapy
- Broad-spectrum antibiotics

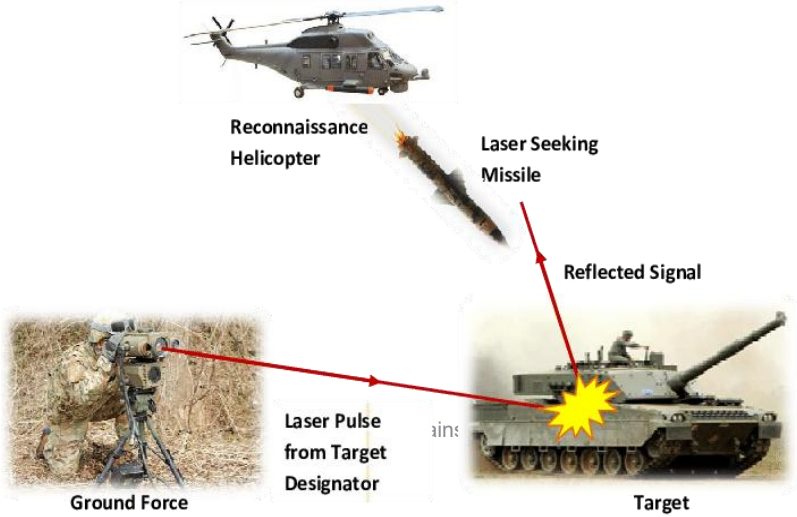
Directed Missile Approach

- Diagnostic imaging plus separate treatment
  - Imaging-directed surgery
  - Imaging then treatment
- Narrow target medications (PCSK9 inhibitors)
- Medications from patient disease (CAR-T)

Laser Gun Approach

- Biologics
- Theranostics
- Gene Therapy

Progression of Targeted Therapeutics



Current Theranostic Landscape

Drug Name	Generic Name	Manufacturer	Mechanism of Action	Indication	Approval Date
Zevalin	Ibritumomab Tiuxetan	Spectrum Therapeutics Biogen Aurobindo Acrotech Biopharma	Anti-CD20 Antibody Radiotherapy	B-cell NHL	2/19/2002
Azedra	Iobenguane I-131	Progenics Lantheus Medical	Electron Transport Inhibitor	Unresectable, metastatic pheochromocytoma or paraganglioma	7/30/2018 (DSC)
Lutathera	Lutetium Lu 177 Dotatate	Advanced Accelerator Applications Novartis	Radiotherapy	SST-positive GEP-NETs	1/26/2018
Pluvicto	Lutetium Lu 177 Vipivotide Tetraxetan	Endocyte Advanced Accelerator Applications Novartis	Radiotherapy	PSMA-positive mCRPC	3/23/2022

CD = cluster of differentiation; DSC = discontinued; GEP-NET = gastroenteropancreatic neuroendocrine tumor; mCRPC = metastatic castration-resistant prostate cancer; NHL = Non-Hodgkin's lymphoma; PSMA = prostate-specific membrane antigen; SST = somatostatin

Future Theranostic Landscape

Pipeline Drug Name	Generic Name	Manufacturer	Mechanism of Action	Pending Indications	Status
Lu 177 Dotatate	Lutetium Lu 177 Dotatate	Curium	Radiotherapy	GEP-NETs	Pending (505b2)
177Lu-Edotreotide	Lutetium Lu 177 Edotreotide	ITM	Radiotherapy	GEP-NETs	Pending
Lu-PNT2002	Lutetium Lu 177 Zadavotide Guraxetan	Point Biopharma Eli Lilly Lantheus Medical	Radiotherapy	Prostate cancer	Phase III
Lu 177 PSMA I&T	Lutetium Lu 177 Zadavotide Guraxetan	Curium	Radiotherapy	Prostate cancer	Phase III
RYZ101	Actinium-225 dotatate	RayzeBio Bristol-Myers Squibb	Radiotherapy	GEP-NETs	Phase III
FPI-2265	TBD	Fusion RadioMedix	Radiotherapy	Prostate cancer	Phase III
AAA817	Actinium Ac 225 Vipivotide Tetraxetan	Advanced Accelerator Applications Endocyte Novartis	Radiotherapy	Prostate cancer	Phase III
TLX591	177Lu Rosopatamab Tetraxetan	Telix	Radiotherapy Anti-PSMA antibody Antibody-drug conjugate	Prostate cancer	Phase III
177Lu-TLX250	Lutetium (177Lu) Girentuximab Tetraxetan	Telix	Radiotherapy Antibody-drug conjugate	Renal cell carcinoma	Phase III

GEP-NET = gastroenteropancreatic neuroendocrine tumor; PSMA = prostate-specific membrane antigen

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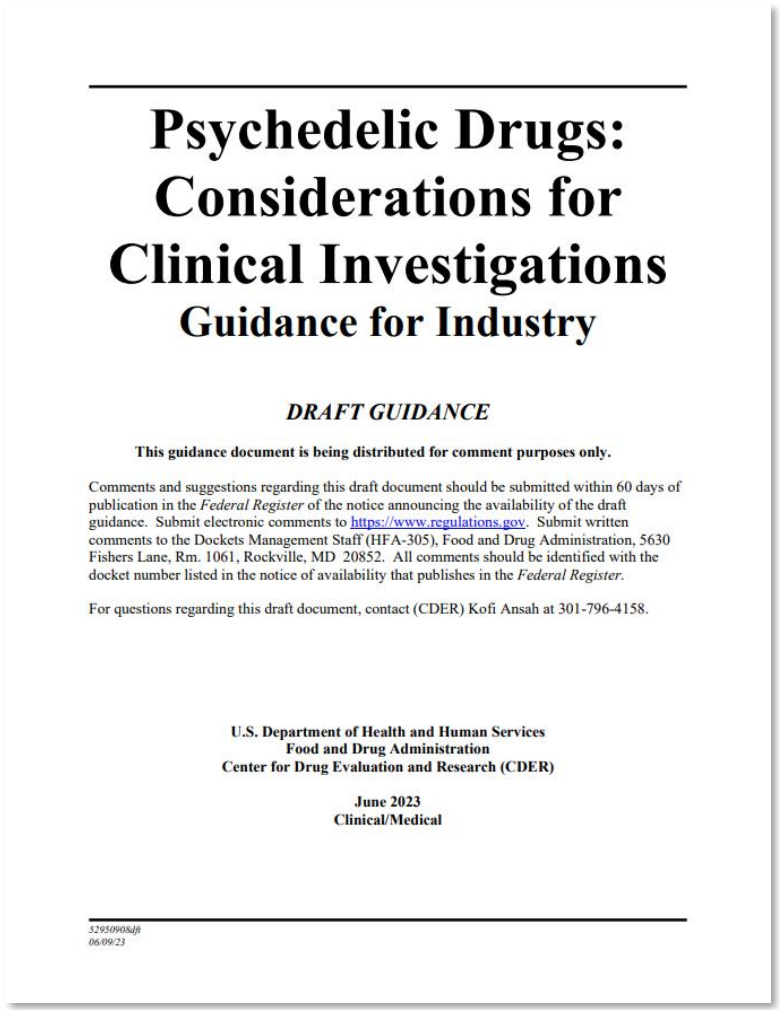
Neuro/Psychedelic Therapies

Neuro/Psychedelic Therapies

- Psychedelics (also known as hallucinogens) are a class of psychoactive substances that produce changes in perception, mood and cognitive processes (i.e. psilocybin, LSD, MDMA & DMT)
- Potential indications: anxiety, depression, tobacco/alcohol addiction, PTSD, & anorexia nervosa
- Currently: 0 FDA approved therapies
- Pipeline: 6 agents in Phase III, 29 agents in Phase II
- FDA Draft Guidance - Psychedelic Drugs: Considerations for Clinical Investigation



Psychedelic Drugs: Considerations for Clinical Investigations

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Kofi Ansah at 301-796-4158.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2023
Clinical/Medical

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Current Neuro/Psychedelic Landscape

Pipeline Drug Name	Generic Name	Route	Manufacturer	Mechanism of Action	Indication	Status
COMP360	Psilocybin	Oral	Compass Pathways	5-HT2A RA	TRD	Phase III
Psilocybin	Psilocybin	Oral	Usona Institute	5-HT2A RA	TRD	Phase III
CYB003	Psilocybin	Oral	Cybin	5-HT2A RA	MDD*	Phase III
MM-120	LSD	Oral (ODT)	MindMed	5-HT2A RA	MDD & GAD	Phase III
MDMA	MDMA	Oral	Lykos Therapeutics	CNS stimulant	PTSD	Phase III^
EMP-01	MDMA	Oral	Atai Life Sciences	CNS stimulant	SAD	Phase III
GM-2505	Bretisilocin	IV	AbbVie	5-HT2A RA & 5-HT Releaser	MDD	Phase II

*Adjunctive MDD treatment
^Received a CRL on 8/9/24 – FDA is requesting an additional Phase 3 study
CNS = central nervous system; GAD = generalized anxiety disorder; LSD = lysergic acid diethylamide; MDD = major depressive disorder; MDMA = methylenedioxymethamphetamine; ODT = orally disintegrating tablet; PTSD = post-traumatic stress disorder; RA = receptor agonist; SAD = social anxiety disorder; TRD = treatment-resistant depression; 5-HT = 5-hydroxytryptamine receptor; 5-HT2A = 5-hydroxytryptamine receptor 2A

Bretisilocin (GM-2505) – Phase 2a Study

NCT06236880	
Study Design	Randomized, double-blind, phase 2a study
Purpose	Evaluate the safety, efficacy and durability of GM-2505 in MDD patients not currently on an antidepressant therapy
Manufacturer	Gilgamesh Pharmaceuticals and AbbVie
Potential Indications	• MDD
Mechanism of Action	• 5-HT2A serotonin receptor agonist
Key Inclusion Criteria	• Age 18-65 years • DSM-5 criteria for MDD • Moderate-severe MDD diagnosis per MADRS-SIGMA • Have not taken a SSRI or SNRI for at least 6 weeks prior to screening • If receiving any form of psychotherapy or counseling must remain on therapy until the end of the study
Key Exclusion Criteria	• Any other DSM-5 diagnosis besides MDD • Family history of schizophrenia, psychosis, bipolar disorder, delusional disorder, paranoid personality disorder or schizoaffective disorder • Current or prior (six weeks before screening) use of any SSRI/SNRI medication, current or prior (five weeks before screening) use of any MAO-I; including phenelzine, tranylcypromine, isocarboxazid, iproniazid, selegiline, rasagiline, the reversible MAO-I moclobemide and the antibiotic linezolid, or any tricyclic antidepressant
Interventions	• Day 1: 10 mg IV or 1 mg IV • Day 15: All patients received 15 mg
Side Effects	• No serious side effects reported; mild side effects typically resolved within two hours following administration
Preliminary Outcomes	• Day 14 change from baseline MADRS score: -21.6 vs -12.1

DSM-5 = The Diagnostic and Statistical Manual of Mental Disorders; MADRS-SIGMA = structured interview guide for the Montgomery-Åsberg depression rating scale; MAO-I = monoamine oxidase inhibitor; MDD = major depressive disorder; SNRI = serotonin-norepinephrine reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor

Implications of Neuro/Psychedelic Therapies

- Challenges:
  - Regulatory barriers (all psychedelics are Schedule I substances)
  - Payer considerations
  - Cost $$$
- Trial concerns
  - Unknown risks/side effects
  - Conducting blinded studies due to the drug's psychoactive effects
  - Small sample sizes
  - Investigator bias

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HIV Pre-exposure Prophylaxis (PrEP)

HIV PrEP

- Approximately 40,000 new HIV diagnoses in the U.S. in 2023
  - Over 1.2 million U.S. adults are eligible for PrEP
  - 36% of those eligible were prescribed PrEP in 2022
- The Centers for Disease Control and Prevention (CDC) guidelines have previously recommended the use of single tablet regimens for maintenance treatment in most patients
- Today, most late-stage pipeline products in development are either long-acting (i.e., monthly or bi-annual dosing) or products designed to treat multi-drug resistant viruses
- Longer-acting oral agents and injectables will be a continuing trend for 2026 and beyond
  - Adherence being the cornerstone of PrEP

Current PrEP Landscape

Brand Name	Generic Name	Manufacturer	Route	Freq.	Mechanism of Action	Approval Date	Generic?	WAC^
Truvada	Emtricitabine/ TDF	Gilead	Oral	Daily	NRTI	8/2/2004	Y	$27.24*
Descovy	Emtricitabine/ TAF	Gilead	Oral	Daily	NRTI	4/4/2016	N	$2,202
Apretude	Cabotegravir	ViiV; GSK	IM	QOM	Integrase Inhibitor	12/20/2021	N	$4,229
Yeztugo	Lenacapavir	Gilead	Oral SC	Q6M	HIV Capsid Inhibitor	6/18/2025	N	Oral: $2,352 SC: $14,109

HIV = human immunodeficiency virus; IM = intramuscular; NRTI = nucleoside reverse transcriptase inhibitor; SC = subcutaneous; Q6M = every 6 months; QOM = every other month; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; WAC = wholesale acquisition cost

^WAC per package as of March 2026

*Generic WAC

Future Landscape of PrEP

Pipeline Drug Name	Generic Name	Brand Company	Route	Frequency	Mechanism of Action	Status
MK-8527	TBD	Merck & Co	Oral	Monthly	NRTTI	Phase III
TBD	Lenacapavir	Gilead	IM	Yearly	HIV Capsid Inhibitor	Phase III
CAB-ULA	Cabotegravir	ViiV; GSK	IM	Q4M	Integrase Inhibitor	Phase II

HIV = human immunodeficiency virus; IM = intramuscular; NRTTI = nucleoside reverse transcriptase translocation inhibitor; Q4M = every 4 months; TBD = to be determined

Lenacapavir – Clinical Trials Overview

	PURPOSE-1 (NCT04994509)	PURPOSE-2 (NCT04925752)
Study Design	Randomized, double-blind, active-controlled (Descovy [F/TAF], Truvada [F/TDF]), phase 3 trial	Randomized, double-blind, active-controlled (Truvada [F/TDF]), phase 3 trial
Purpose	Evaluated the safety and efficacy of twice-yearly SC lenacapavir or daily oral F/TAF for HIV prevention in **adolescent girls and young women**	Evaluated the safety and efficacy of twice-yearly SC lenacapavir for prevention of HIV infection in **cisgender gay, bisexual, and other men, transgender women, transgender men, and gender-nonbinary persons** who have sex with partners assigned male at birth.
Study Locations	• South Africa and Uganda	• Argentina, Brazil, Mexico, Peru, South Africa, Thailand, and the United States
Key Inclusion Criteria	• Adolescent girls and young women (age 16-25 years) • Sexually active with male partners, not using PrEP • Unknown HIV status and no HIV testing within the previous 3 months	• Cisgender gay, bisexual, and other men, transgender women, transgender men, and gender-nonbinary persons (age ≥16 years) • Condomless receptive anal sex with partners assigned male at birth • Unknown HIV status and no HIV testing/PrEP use in the 3 months before screening
Key Exclusion Criteria	• Prior use of long-active systemic PrEP	• Prior use of long-active systemic PrEP • Acute viral hepatitis A, B, or C; evidence of chronic hepatitis B or C infection • Suspected or known active, serious infection • History of osteoporosis or bone fragility fractures
Interventions	• Randomization in a 2:2:1 ratio to receive: ○ Lenacapavir 927 mg (two 1.5 mL injections) SC every 26 weeks (±7 days) ○ F/TAF (200 mg emtricitabine, 25 mg TAF) once daily ○ F/TDF (200 mg emtricitabine, 300 mg TDF) once daily	• Randomization in a 2:1 ratio to receive: ○ Lenacapavir 927 mg (two 1.5 mL injections) SC every 26 weeks (±7 days) ○ F/TDF (200 mg emtricitabine, 300 mg TDF) once daily
Key Efficacy Outcomes	• Primary ○ New HIV infection • Secondary ○ Incidence rate ratio compared participants who received lenacapavir or F/TAF with F/TDF HIV incidence	• Primary ○ New HIV infection • Secondary ○ Incidence rate ratio compared participants who received lenacapavir with F/TDF HIV incidence
Key Safety Outcomes	• Adverse events and clinical laboratory abnormalities	• Adverse events and clinical laboratory abnormalities

F/TAF = emtricitabine/tenofovir alafenamide; F/TDF = emtricitabine/tenofovir disoproxil fumarate; HIV = human immunodeficiency virus; PrEP = preexposure prophylaxis; SC = subcutaneous

Yeztugo Study Overview HIV Infection Incidence

	PURPOSE-1 (N=5,338)			PURPOSE-2 (N=3,265)	
	LEN (n=2,134)	**F/TAF (n=2,136)**	**F/TDF (n=1,068)**	**LEN (n=2,179)**	**F/TDF (n=1,086)**
Incidence of HIV infections per 100-person years	0.00	2.02	1.69	0.10	0.93
Number of infections	0	39	16	2	9
Total person years	1939	1932	949	1938	967
Primary outcome					
Incidence rate ratio compared to background HIV incidence (95% CI)	**0.00 (0.00, 0.04)**	0.84 (0.55, 1.28)	---	**0.04 (0.01, 0.18)**	---
Secondary outcome					
Incidence rate ratio compared to F/TDF HIV incidence (95% CI)	**0.00 (0.00, 0.10)**	1.20 (0.67, 2.14)	Reference	**0.11 (0.02, 0.51)**	Reference
Adverse events, n (%)					
Injection site reactions, n/total n (%)	1470 (68.8)	755 (35.3)	363 (33.9)	1816 (83.2)	756 (69.5)
Nausea, n (%)	144 (6.7)	234 (10.9)	142 (13.3)	89 (4.1)	67 (6.2)
Diarrhea, n (%)	133 (6.2)	161 (7.5)	67 (6.3)	146 (6.7)	75 (6.9)

CI = confidence interval; F/TAF = emtricitabine/tenofovir alafenamide; F/TDF = emtricitabine/tenofovir disoproxil fumarate; HIV = human immunodeficiency virus; LEN = lenacapavir

Once-Yearly Lenacapavir – PURPOSE 365

NCT07047716	
Study Design	Multicenter, open-label, single-arm, phase 3 study
Purpose	Evaluate the pharmacokinetics, safety, and tolerability of once-yearly PrEP therapy with IM lenacapavir
Study Locations	United States

Key Inclusion Criteria	• Age ≥16 years at screening
	• Condomless receptive sex in the past 6 months and ≥1 of the following:
	  ○ 1 or more sexual partners of unknown HIV status in the previous 6 months
	  ○ Diagnosis of syphilis, gonorrhea, or chlamydia in the past 6 months
	  ○ Sex with a partner known to be living with HIV with an unknown or detectable viral load in the previous 6 months
	• Negative HIV test at screening

Key Exclusion Criteria	• Current signs or symptoms of HIV infection • Acute viral hepatitis A, B, or c, or evidence of chronic hepatitis B or C infection • Severe hepatic impairment or history of or current clinical decompensated liver cirrhosis • Past/current participation in HIV vaccine study unless documentation of placebo receipt • Prior use of oral lenacapavir in the previous 90 days or SC lenacapavir in the previous 18 months
Interventions	• Lenacapavir 3000 mg IM on day 1 *and* • Lenacapavir 600 mg orally on days 1 and 2
Key Efficacy Outcomes	• Plasma lenacapavir trough at week 52
Key Safety Outcomes	• Percentage of patients experiencing treatment-emergent adverse events • Percentage of patients experiencing treatment-emergent clinical laboratory abnormalities • Discontinuation due to adverse events
Expected Completion	• September 2028

HIV = human immunodeficiency virus; IM = intramuscular; PrEP = preexposure prophylaxis

Pharmacy Techs

Assessment Question #4

HIV PrEP is usually prescribed as a once daily therapy. Which of the following HIV medications has a new potential pipeline frequency of yearly?

A. Lenacapavir
B. Cabotegravir
C. Emtricitabine/TAF
D. Emtricitabine/TDF

Pharmacy Techs

Assessment Question #4: Correct Response

HIV PrEP is usually prescribed as a once daily therapy. Which of the following HIV medications has a new potential pipeline frequency of yearly?

A. **Lenacapavir**
B. Cabotegravir
C. Emtricitabine/TAF
D. Emtricitabine/TDF

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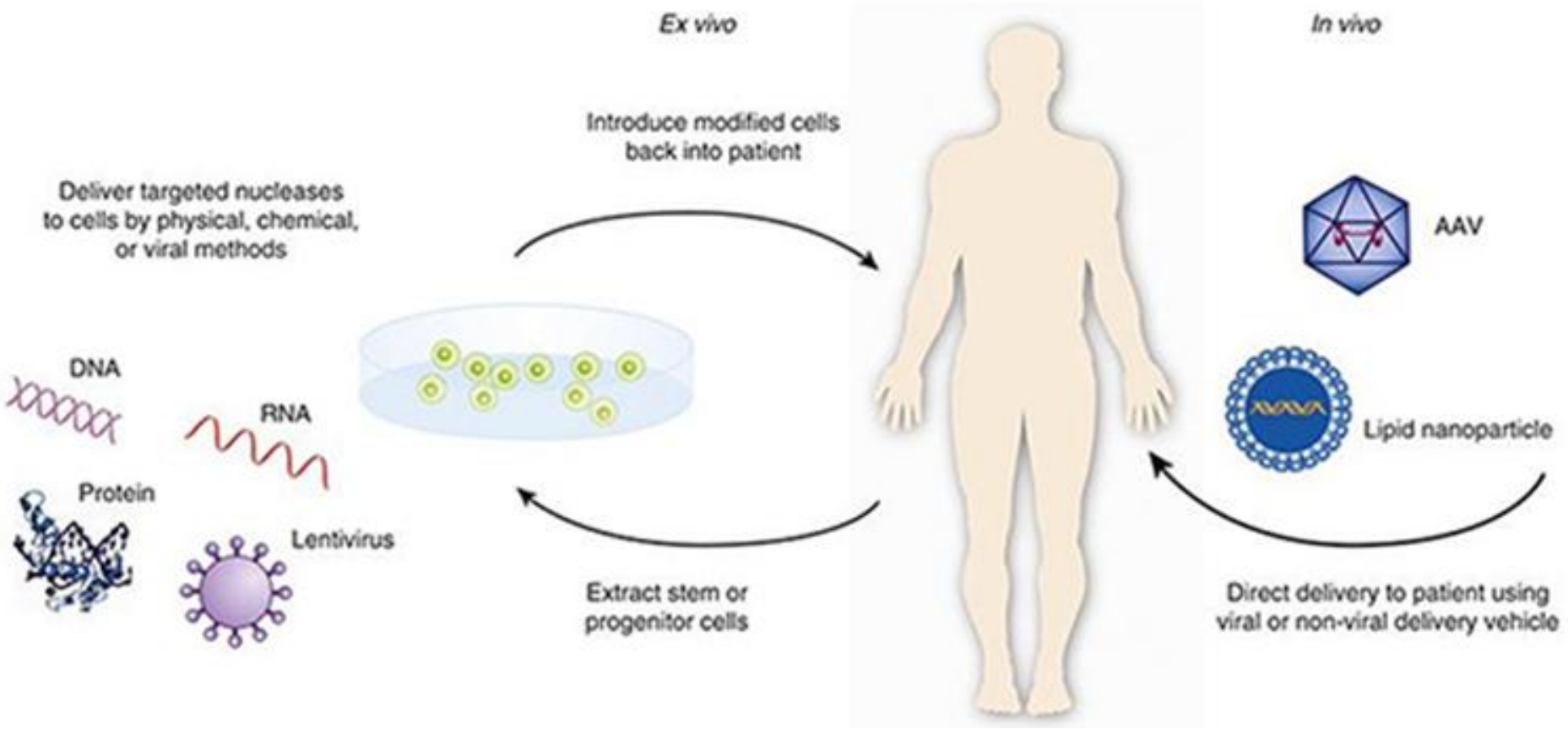
Gene Therapy

Gene & Cell Therapy

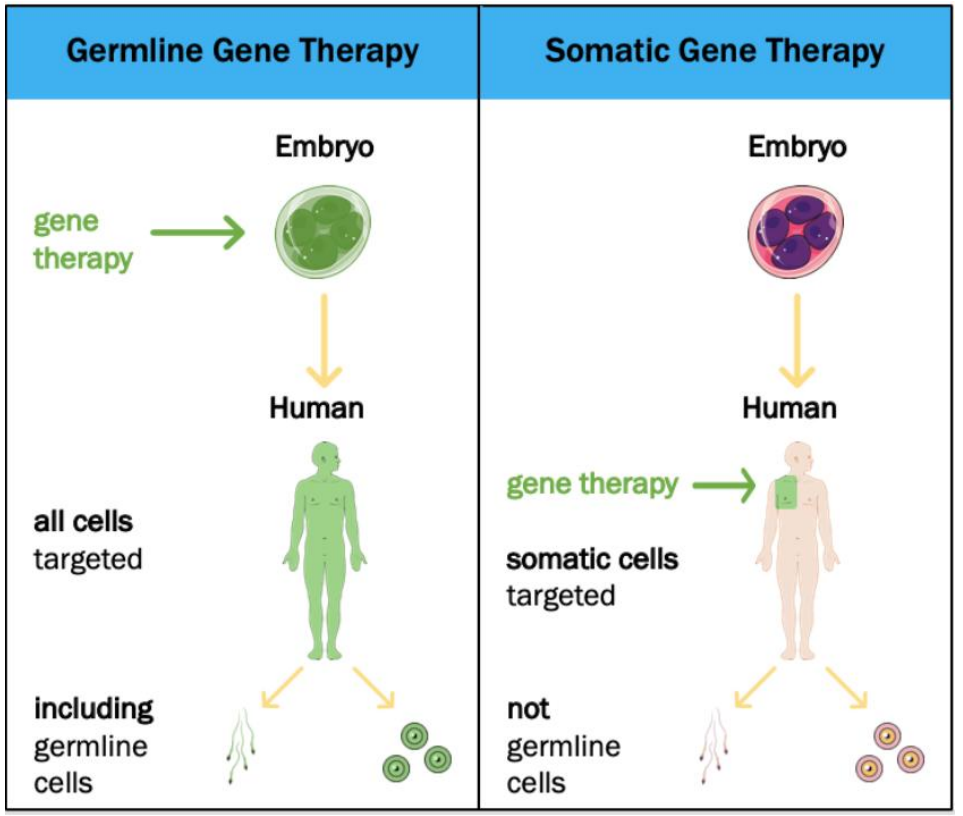
- **Gene therapy** seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use
- Gene therapies can work via several mechanisms:
  - Replace a disease-causing gene with a healthy copy of the gene
  - Inactivate a disease-causing gene that is not functioning properly
  - Introduce a new or modified gene into the body to help treat a disease
- **Cell therapy** refers to the process where targeted cells are removed and altered outside of the patient's body, followed by a transfusion that delivers the altered cells back into the patient

Gene Therapy



Gene Therapy Considerations

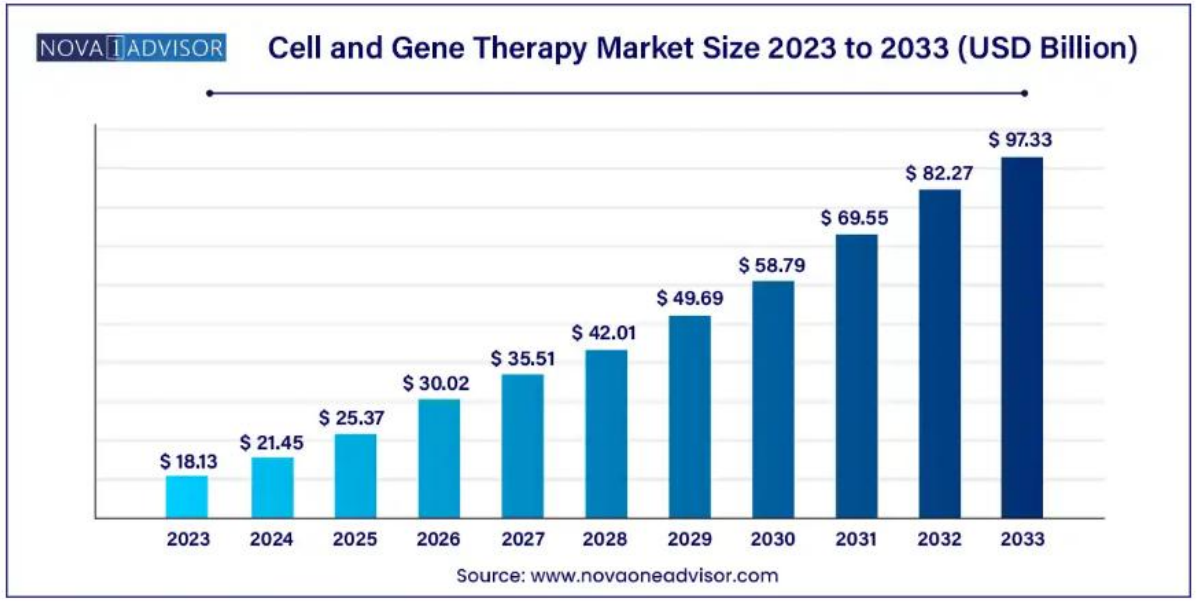
- Changes to the DNA are permanent/semi permanent
  - Route of delivery changes the sustainability of the treatment
  - Rapidly dividing cells needs integration of gene into genome
- Changes to the DNA are not passed to offspring
  - Somatic gene therapy
- Gene therapy is not the same as “Germline editing”
  - Germline editing would be permanent and passed to offspring
  - Germline ethics have not been clearly defined in the market
  - Unknown impact to future generations
  - Inability to consent



Germline Vs. Somatic Gene Therapy. Image created by Sonya Frazier

Current Gene Therapy Landscape

- Today there are **28 FDA approved** therapies with **7** additional pending FDA approval
- In the near-term pipeline (Phase III), we have **35** therapies, **29** of which are first time treatments in the gene therapy space
  - **21** are for rare diseases and **14** are for common diseases
- High-cost medications, especially for one-time gene therapies approved for rare-diseases vs CAR-T cell gene therapies
  - Most expensive = Lenmeldy at $4.25 million for metachromatic leukodystrophy
- Complex payer management



FDA Approved Gene Therapies

Gene Therapy	Indication	Mechanism of Action	Approval Date	Cost
Kymriah (tisagenlecleucel-t)	Acute lymphocytic leukemia; B-cell lymphoma; Diffuse large B-cell lymphoma; Follicular lymphoma	Chimeric antigen receptor T-cell (CAR-T) immunotherapy Cellular immunotherapy	8/30/2017	$523,152
Yescarta (axicabtagene ciloleucel)	B-cell lymphoma; Diffuse large B-cell lymphoma; Primary mediastinal large B-cell lymphoma; Follicular lymphoma	Chimeric antigen receptor T-cell (CAR-T) immunotherapy Cellular immunotherapy	10/18/2017	$548,900
Luxturna (voretigene neparvovec)	Inherited retinal disease (IRD)	Gene therapy	12/19/2017	$913,750
Zolgensma (onasemnogene abeparvovec)	Spinal muscular atrophy	Gene therapy	5/24/2019	$2,586,630
Tecartus (brexucabtagene autoleucel)	Mantle cell lymphoma; Acute lymphocytic leukemia	Chimeric antigen receptor T-cell (CAR-T) immunotherapy Cellular immunotherapy	7/24/2020	$503,580
Breyanzi (lisocabtagene maraleucel)	B-cell lymphoma; Diffuse large B-cell lymphoma; Follicular lymphoma; Primary mediastinal large B-cell lymphoma; Chronic lymphocytic leukemia; Mantle cell lymphoma	Chimeric antigen receptor T-cell (CAR-T) immunotherapy Cellular immunotherapy	2/5/2021	$557,918
Abecma (idecabtagene vicleucel)	Multiple myeloma	Chimeric antigen receptor T-cell (CAR-T) immunotherapy Cellular immunotherapy	3/26/2021	$544,162
Carvykti (ciltacabtagene autoleucel)	Multiple myeloma	Chimeric antigen receptor T-cell (CAR-T) immunotherapy Cellular immunotherapy	2/28/2022	$555,310
Zynteglo (betibeglogene autotemcel)	Beta thalassemia	Gene therapy	8/17/2022	$2,800,000
Skysona (elivaldogene autotemcel)	Cerebral adrenoleukodystrophy (CALD)	Gene therapy	9/16/2022	$3,000,000
Hemgenix (etranacogene dezaparvovec)	Hemophilia B	Gene therapy	11/22/2022	$3,500,000

FDA Approved Gene Therapies

Gene Therapy	Indication	Mechanism of Action	Approval Date	Cost
Adstiladrin (nadofaragene firadenovec)	Non-muscle invasive bladder cancer	Gene therapy	12/16/2022	$243,600
Vyjuvek (beremagene geperpavec)	Epidermolysis bullosa	Gene therapy	5/19/2023	$1,352,000
Elevidys (delandistrogene moxeparvovec)	Muscular Dystrophy	Gene therapy	6/22/2023	$3,200,000
Roctavian (valoctocogene roxaparvovec)	Hemophilia A	Gene therapy	6/29/2023	$3,031,840
Casgevy (exagamglogene autotemcel)	Sickle cell disease and beta thalassemia	CRISPR gene editing	12/8/2023	$2,200,000
Lyfgenia (lovotibeglogene autotemcel)	Sickle cell disease	Gene therapy	12/8/2023	$3,100,000
Lenmeldy (atidarsagene autotemcel)	Metachromatic leukodystrophy	Gene therapy	3/18/2024	$4,250,000
Beqvez (fidanacogene elaparvovec)	Hemophilia B	Gene therapy	4/25/2024	- -
Tecelra (afamitresgene autoleucel)	Synovial sarcoma	Gene therapy Natural T-cell receptor (TCR) immunotherapy Cellular immunotherapy	8/1/2024	$781,525
Aucatzyl (obecabtagene autoleucel)	Acute lymphocytic leukemia	Chimeric antigen receptor T-cell (CAR-T) immunotherapy	11/8/2024	$525,000
Kebilidi (eladocagene exuparvovec)	Aromatic L-amino acid decarboxylase deficiency	Gene therapy	11/13/2024	$3,950,000
Encelto (revakinagene taroretcel)	Macular telangiectasia	Gene therapy Nerve growth factor (recombinant) Allogeneic cellular product	3/5/2025	$250,000
Zevaskyn (prademagene zamikeracel)	Recessive dystrophic epidermolysis bullosa	Gene therapy Autologous cellular product	4/28/2025	$3,147,000
Papzimeos (zopapogene imadenovec)	Recurrent respiratory papillomatosis	Gene therapy Antigen-specific immunotherapy	8/14/2025	$460,000
Itvisma (onasemnogene abeparvovec)	Spinal muscular atrophy	Gene therapy	11/24/2025	$2,586,630
Breyanzi (lisocabtagene maraleucel)	Follicular lymphoma; Acute lymphocytic leukemia; B-cell lymphoma; Central nervous system lymphoma; Marginal zone lymphoma	Chimeric antigen receptor T-cell (CAR-T) immunotherapy Cellular immunotherapy	12/4/2025	- -
Waskyra (etuvetidigene autotemcel)	Wiskott-aldrich syndrome	Gene therapy	12/9/2025	- -

Expected Gene Therapy Approvals in 2026

Drug Name	Generic Name	Brand Company	Mechanism of Action	Indication	Expected Approval
RGX-121	Clemidsogene Lanparvovec	Regenxbio Nippon Shinyaku	Gene therapy	Mucopolysaccharidosis Type 2	CRL (02/09/2026)
RP-L102	Mozafancogene Autotemcel	Rocket Pharma	Gene therapy	Fanconi Anemia	Pending (voluntarily withdrew BLA)
DTX401	Pariglasgene Brecaparvovec	Ultragenyx	Gene therapy	Von Gierke disease	2H 2026
MCO-010	Sonpiretigene Isteparvovec	Nanoscope Therapeutics	Gene therapy	Retinitis pigmentosa Stargardt disease	Pending
INO-3107	Doruxapapogene Ralaplasmid	Inovio	Gene therapy Antigen-specific immunotherapy	Recurrent respiratory papillomatosis (RRP)	10/30/2026
Kresladi	Marnetegragene Autotemcel	Rocket Pharma	Gene therapy	Leukocyte Adhesion Defect Type 1	03/28/2026
ST-920	Isaralgagene Civaparvovec	Sangamo Therapeutics	Gene therapy	Fabry Disease	Pending

Current Gene Therapy Landscape

Key Statistics

- 35 Gene Therapy Candidates in Phase 3 Clinical Trials
- 21 for rare disease – 14 for common disease
- 29/35 are first in class
- Ocular, muscular, oncologic, common, & misc.

Pipeline Drug Name	Generic Name	Brand Company	Mechanism of Action	Indication	Status
GS010	Lenadogene Nolparvovec	GenSight Biologics Genethon	Gene therapy	Leber's hereditary optic neuropathy	Phase III
OCU400	TBD	Ocugen	Gene therapy	Retinitis pigmentosa	Phase III
AAV-RPGR	Botaretigene Sparoparvovec	MeiraGTx Johnson & Johnson (Janssen)	Gene therapy	Retinitis pigmentosa	Phase III
AGTC-501	Laruparetigene Zovaparvovec	Applied Genetic Technologies Beacon Therapeutics	Gene therapy	Retinitis pigmentosa	Phase III
KB803	Beremagene Geperpavec	Krystal Biotech	Gene therapy	Ocular complications of dystrophic epidermolysis bullosa	Phase III
OCU410ST	TBD	Ocugen	Gene therapy	Stargardt disease	Phase III
SB-525	Giroctocogene Fitelparvovec	Sangamo Therapeutics Pfizer	Gene therapy	Hemophilia A	Phase III
D-Fi	Dabocemagene Autoficel	Castle Creek Biosciences Paragon Biosciences Fibrocell Technologies Intrexon	Gene therapy	Epidermolysis bullosa	Phase III
UX701	Rivunatpagene Miziparvovec	Ultragenyx	Gene therapy	Wilson's disease	Phase III
Descartes-08	TBD	Cartesian Therapeutics	Gene therapy	Myasthenia gravis; Systemic lupus erythematosus; Multiple myeloma	Phase III
DTX301	Avalotcagene Ontaparvovec	Ultragenyx Regenxbio	Gene therapy	Ornithine transcarbamylase (OTC) deficiency	Phase III
LYS-SAF302	Olenasufligene Relduparvovec	Lysogene	Gene therapy	Mucopolysaccharidosis type IIIA	Phase III
OTL-203	TBD	Orchard Therapeutics Kyowa Kirin	Gene therapy	Mucopolysaccharidosis type I, Hurler subtype (MPS-IH)	Phase III
FLT201	Avigbagene Parvec	Spur Therapeutics	Gene therapy	Gaucher disease, Type 1	Phase III
NTLA-2002	Lonvoguran Ziclumeran	Intellia Therapeutics	Gene therapy	Hereditary angioedema	Phase III
Melpida	TBD	Elpida Therapeutics	Gene therapy	Hereditary spastic paraplegia	Phase III
NTLA-2001	Nexiguran Ziclumeran	Intellia Therapeutics Regeneron	Gene therapy	Transthyretin amyloid cardiomyopathy	Phase III
SRP-9003	Bidridistrogene Xeboparvovec	Sarepta Myonexus Therapeutics	Gene therapy	Limb-girdle muscular dystrophy	Phase III

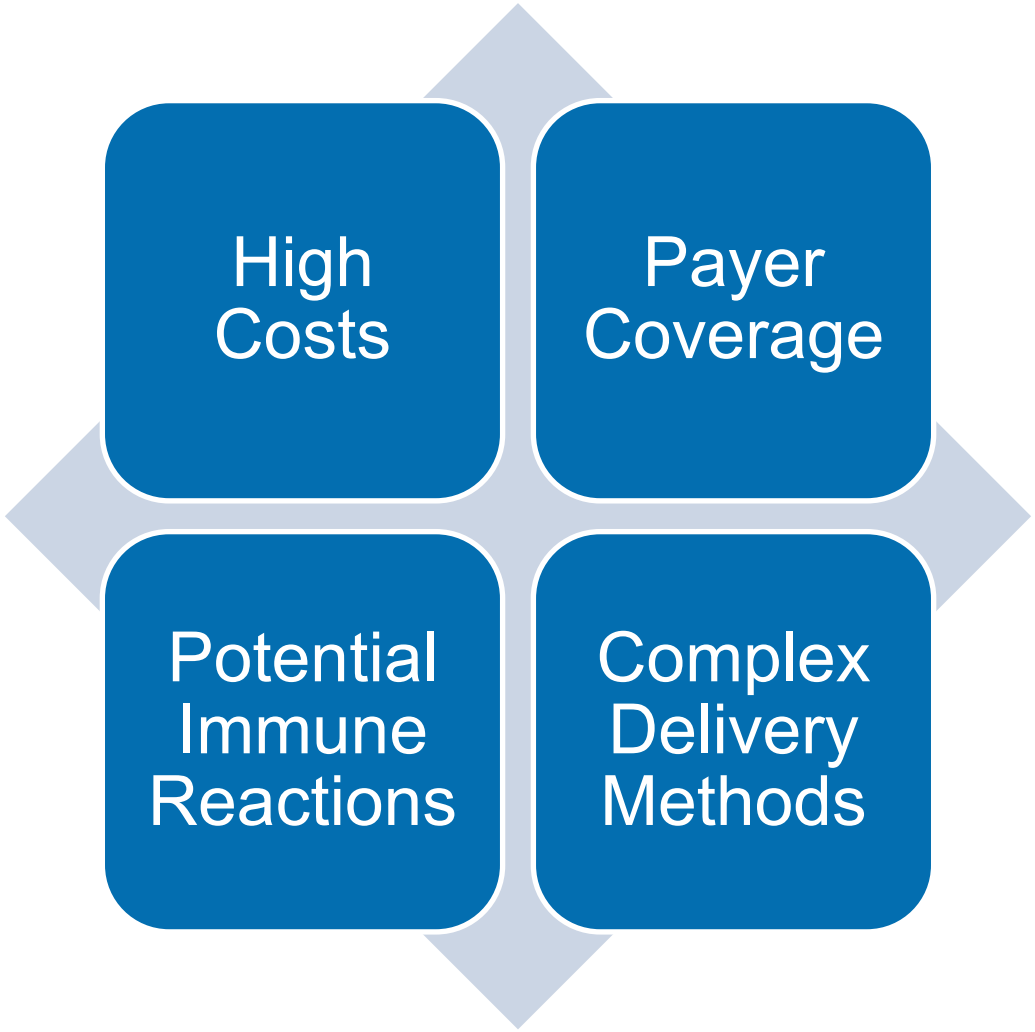
Current Gene Therapy Landscape

Key Statistics

- 35 Gene Therapy Candidates in Phase 3 Clinical Trials
- 21 for rare disease – 14 for common disease
- 29/35 are first in class
- Ocular, muscular, oncologic, common, & misc.

Pipeline Drug Name	Generic Name	Brand Company	Mechanism of Action	Indication	Status
SRP-9005	TBD	Myonexus Therapeutics Sarepta	Gene therapy	Limb-girdle muscular dystrophy	Phase III
RGX-202	TBD	Regenxbio	Gene therapy	Duchenne muscular dystrophy	Phase III
SGT-003	TBD	Solid Biosciences	Gene therapy	Duchenne muscular dystrophy	Phase III
Generx	Alferminogene Tadenovec	Angionetics Gene Biotherapeutics	Gene therapy	Myocardial ischemia and refractory angina due to coronary artery disease (CAD)	Phase III
4D-150	TBD	4D Molecular Therapeutics	Gene therapy	Wet age-related macular degeneration; Diabetic macular edema	Phase III
ADVM-022	Ixoberogene soroparvovec	Adverum Biotechnologies	Gene therapy	Wet age-related macular degeneration	Phase III
RGX-314	Surabgene Lomparvovec	Regenxbio AbbVie	Gene therapy	Diabetic retinopathy	Phase III
Invossa	Tonogenchoncel-L	Kolon	Gene therapy	Chronic degenerative joint disease (osteoarthritis)	Phase III
LBP-EC01	TBD	Locus	Gene therapy	Urinary tract infection	Phase III
Engensis	Donaperminogene Seltoplasmid	ViroMed Helixmith	Gene therapy	Diabetic neuropathy	Phase III
KITE-772	Anitocabtagene Autoleucel	Arcellx Kite Pharma Gilead	Gene therapy	Multiple myeloma	Phase III
BMS-986393	Arlocabtagene Autoleucel	Bristol-Myers Squibb Juno Therapeutics	Gene therapy	Multiple myeloma	Phase III
Adstiladrin	Nadofaragene Firadenovec	FKD Therapies Ferring Pharmaceuticals Trizell Merck & Co (MSD) FerGene	Gene therapy	Mesothelioma	Phase III
IMNN-001	TBD	Celsion Imunon	Gene therapy	Ovarian cancer	Phase III
CAN-2409	Aglatimagene Besadenovec	Candel Therapeutics	Gene therapy	Prostate cancer; Pancreatic cancer; Non-small cell lung cancer (NSCLC)	Phase III
CEA CAR-T	TBD	Sorrento Therapeutics	Gene therapy	Pancreatic cancer	Phase III
IMA203	Anzutresgene Autoleucel	Immatics	Gene therapy	Melanoma	Phase III

Implications of Gene Therapies



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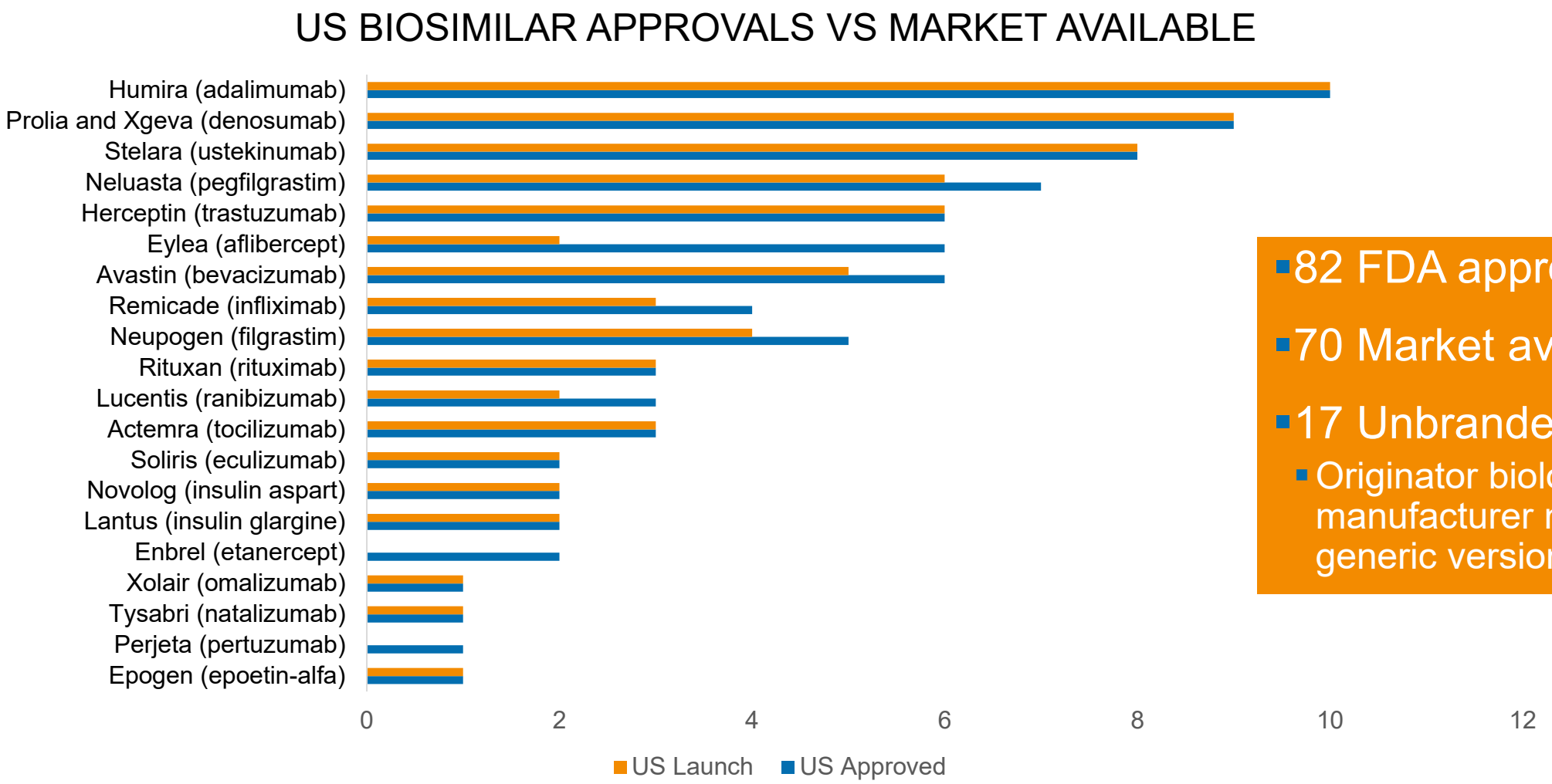
Biosimilars

Current State of the Biosimilar Market



- 82 FDA approved
- 70 Market available
- 17 Unbranded biologics
  - Originator biologic manufacturer makes a generic version

Expected Biosimilar Approvals in 2026

Pipeline Drug Name	Manufacturer	Route	Pending Indication(s)	Expected Approval
Orencia IV (abatacept)				
DRL_AB	Dr. Reddy's	Intravenous	Psoriatic and rheumatoid arthritis	12/2026
Eylea (aflibercept)				
SCD411	Fresenius Kabi	Intravitreal	Diabetic retinopathy and macular degeneration	10/2026
Avastin (bevacizumab)				
HLX04	Henlius	Intravenous	Oncologic misc.	Q4 2026
Prolia & Xgeva (denosumab)				
ENZ215-P (Prolia Biosimilar)	Alkem Labs	Subcutaneous	Bone cancer, multiple myeloma & tumors	Q2 2026
ENZ215-X (Xgeva Biosimilar)	Alkem Labs	TBD		Q2 2026
Simponi/Simponi Aria (golimumab)				
BAT2506	Bio-Thera Solutions	Subcutaneous	Ankylosing spondylitis, inflammatory bowel disease, psoriatic & rheumatoid arthritis	5/16/2026
Xolair (omalizumab)				
ADL-018	Amneal	Subcutaneous	Idiopathic urticaria	Q4 2026
Perjeta (pertuzumab)				
PERT-IJS	Biocon	Intravenous	Breast cancer	Q4 2026
Lucentis (ranibizumab)				
LUBT010	Lupin	Intravitreal	Macular degeneration	6/2026
Herceptin (trastuzumab)				
TX05	Tanvex	Injectable	Breast cancer, gastric cancer	6/2026

Expectations for 2026

- 19 biosimilars are pending FDA decision
- Entry into the biosimilar market
  - Simponi, Simponi Aria
- 34 biosimilars are currently in phase III clinical trials
- The Biosimilar Forum proposed legislation for the Senate Finance Committee which requires Part D plans to offer biosimilars priced at least 45% lower than the reference biologic
  - Expected to start in 2026
- Faster and less costly biosimilar development
  - FDA Draft Guidance - Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies
  - March 2026: New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)

Interchangeable Biosimilar

- Interchangeable designation means a biosimilar may be substituted for its reference product at the pharmacy, without additional approvals from the prescriber, state law permitting
- Requires clinical studies to demonstrate no safety or efficacy impact when a patient switches back and forth between reference and biosimilar product
- Interchangeability is unique to the US market
  - 47 states in the US allow for interchangeability
  - In the European Union, the decision to allow interchangeability lies with each member state and does not require additional testing
  - Japan and Iran allow automated biosimilar substitution
  - 24 currently approved interchangeable biosimilars in the U.S.
- October 2025 FDA Draft Guidance: (Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies) may eliminate the need for clinical efficacy and switching studies
- March 2026: New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)

Assessment Question #5

Pharmacy Techs

According to the FDA's New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4), how is the Agency's approach to demonstrating interchangeability for biosimilars evolving?

A. The FDA now requires switching studies for all biosimilars, regardless of clinical experience or analytical similarity

B. The FDA indicates that switching studies may not be necessary when strong analytical and clinical evidence supports that switching does not increase risk

C. The FDA has eliminated the interchangeability designation entirely and will no longer review such applications

D. The FDA requires only *in vitro* data for interchangeability determinations, with no clinical or analytical data needed

Assessment Question #5

Pharmacy Techs

According to the FDA's New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4), how is the Agency's approach to demonstrating interchangeability for biosimilars evolving?

A. The FDA now requires switching studies for all biosimilars, regardless of clinical experience or analytical similarity

B. **The FDA indicates that switching studies may not be necessary when strong analytical and clinical evidence supports that switching does not increase risk**

C. The FDA has eliminated the interchangeability designation entirely and will no longer review such applications

D. The FDA requires only *in vitro* data for interchangeability determinations, with no clinical or analytical data needed

Pharmacists, Nurses & Healthcare Executives

Assessment Question #6

All of the following are key therapeutic classes addressed in this presentation EXCEPT?

A. HIV PrEP
B. Anti-infectives
C. GLP-1s
D. Biosimilars

Pharmacists, Nurses & Healthcare Executives

Assessment Question #6: Correct Response

All of the following are key therapeutic classes addressed in this presentation EXCEPT?

A. HIV PrEP
B. Anti-infectives
C. GLP-1s
D. Biosimilars

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Thank You!

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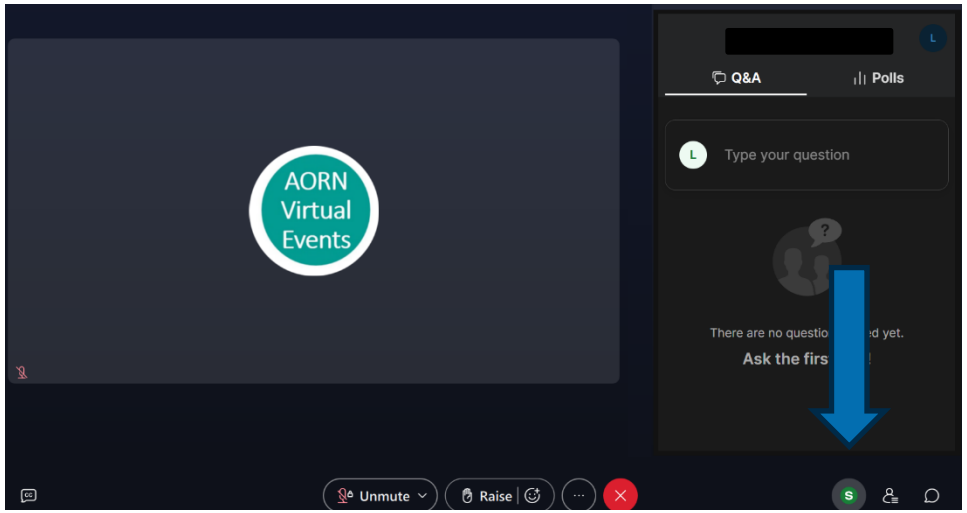

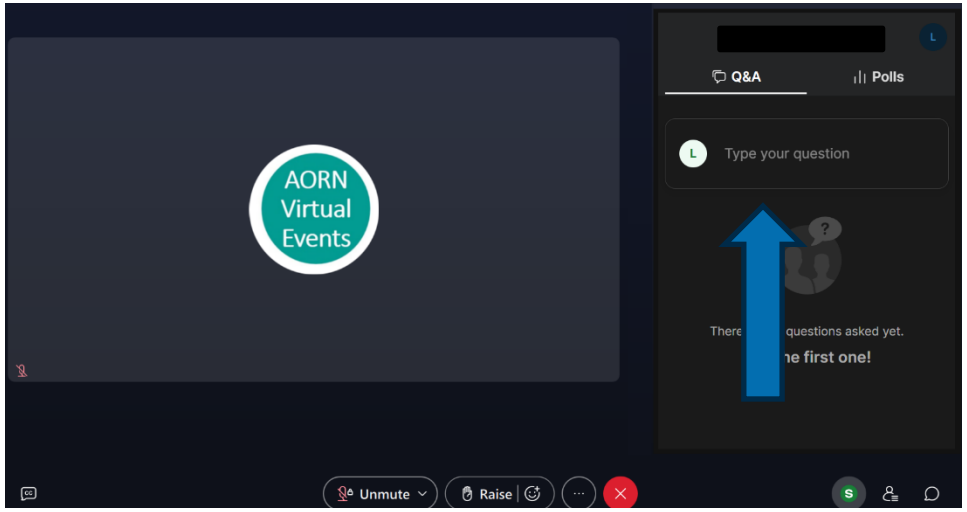

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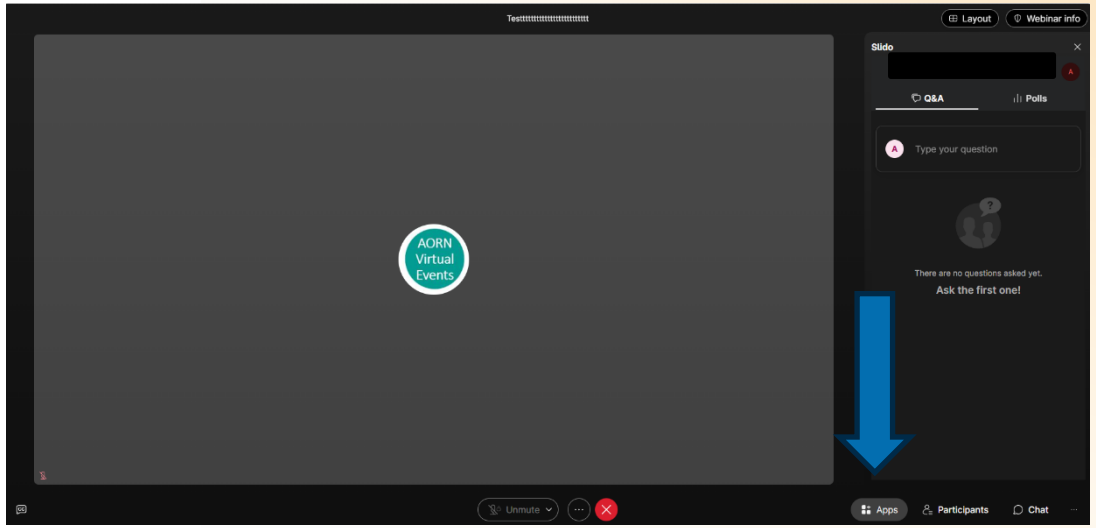

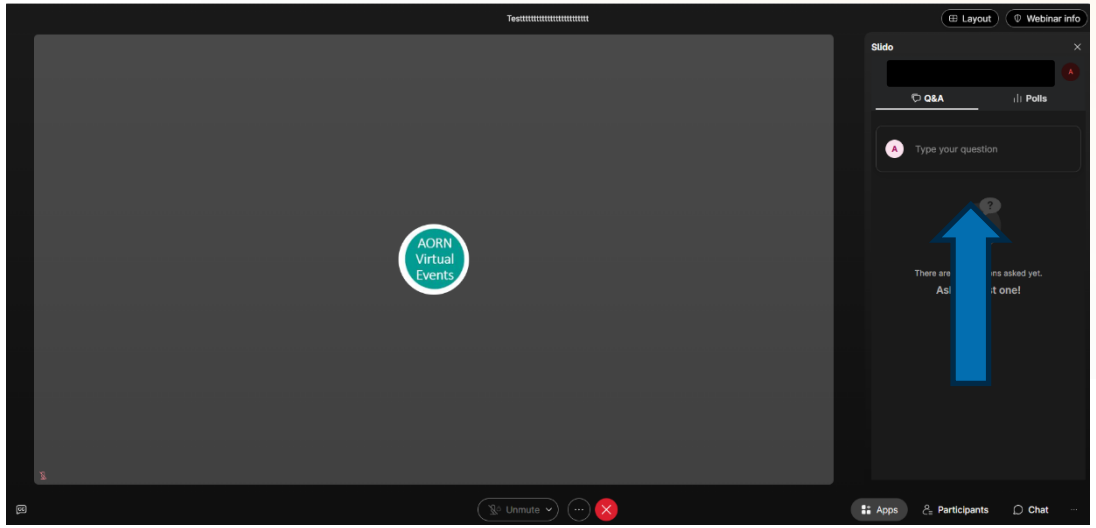

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