Kroger Prescription Plans

2024 Drug Pipeline Digest

This overview will explore some latest advancements in medicine with a review and summary of the 2024 drug pipeline. This publication delves into recent drug research, providing insights into potential breakthroughs that may significantly impact healthcare. Learn about the purpose, mechanism, and anticipated approval timelines of these drugs to understand potential changes that may impact your organization.

KarXT (Xanomeline/Tropsium Chloride)
by Karuna Therapeutics

Insulin Icodec
by Novo Nordisk

TransCon PTH (palopegteriparatide)
by Ascendis

MGL-3196 (Resmetirom)
by Madrigal Pharmaceuticals

ACE-011 (Sotatercept) *by Acceleron / Celgene Bristol-Myers Squibb / Merck & Co*

MIN-101 (Roluperidone)
by Minerva / Mitsubishi Tanabe

ACT-132577 (Aprocitentan)
by Idorsia / Johnson & Johnson (Janssen)

Vafseo (Vadadustat)
by Akebia Therapeutics / Fresenius Kabi

800.917.4926
www.kpp-rx.com

KarXT (Xanomeline/Tropsium Chloride)
by Karuna Therapeutics

Indication(s): Psychosis in schizophrenia, inadequate response in schizophrenia, and psychosis in Alzheimer's
Mechanism of Action (MOA): Muscarinic receptor agonist/muscarinic receptor antagonist
Route of Administration: Oral
Anticipated Approval Date/Status: PDUFA date for this agent is September 26, 2024
Estimated Price: $20,000–$50,000 per year
Drug Highlights: This novel combination selectively activates brain receptors, minimizing peripheral side effects. Phase 3 trials (EMERGENT-2, -3, -4, -5) target schizophrenia, ARISE assesses inadequate responses, and Adept-1 explores Alzheimer's. If successful, this novel approach may establish a new standard for schizophrenia monotherapy.

Insulin Icodec
by Novo Nordisk

Indication(s): Improve glycemic control in type 1 and 2 diabetes
Mechanism of Action: Insulin/insulin analog
Route of Administration: Subcutaneous
Anticipated Approval Date/Status: 2Q 2024
Estimated Price: < $5,000 per year
Drug Highlights: This weekly basal insulin, showed efficacy and safety in phase 2 trials, with promising results in reducing HbA1c compared to daily insulin glargine U100. Phase 3 trials, including ONWARDS 1, 2, 3, 4, 5, and 6, consistently demonstrated non-inferiority and superior HbA1c reduction compared to Lantus, Tresiba, and other basal insulins in both type 1 and type 2 diabetes. The data supports potential first-in-class once-weekly basal insulin, offering convenience and improved glycemic control.

TransCon PTH (palopegteriparatide)
by Ascendis

Indication(s): Hypoparathyroidism
Mechanism of Action: Prodrug of parathyroid hormone (PTH) or analog
Route of Administration: Subcutaneous
Anticipated Approval Date/Status: Pending 05/14/2024
Estimated Price: $100,000–$300,000 per year
Drug Highlights: Phase 3 trials showed 78.7% achieving normalized serum calcium and independence from conventional therapy, outperforming Natpara. With a unique delivery technology, it promises stability, improved quality of life, and the potential to replace standard treatments, positioning TransCon PTH as the

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MGL-3196 (Resmetirom)
by Madrigal Pharmaceuticals

Indication(s): Non-alcoholic steatohepatitis (NASH)
Mechanism of Action: Thyroid hormone receptor agonist
Route of Administration: Oral
Anticipated Approval Date/Status: PDUFA date of March 14, 2024
Estimated Price: $20,000–$50,000 per year
Drug Highlights: Recent MAESTRO-NAFLD-1 phase 3 results showcase its significant efficacy, with a 48% reduction in liver fat compared to placebo. The ongoing MAESTRO-NASH study, coupled with positive data and accelerated approval potential, underlines resmetirom's pivotal role in transforming NASH management. It reduces lipotoxicity and may be differentiated by its potential cardiovascular benefits. It has the potential to be the first approved therapy for NASH.

ACE-011 (Sotatercept) *by Acceleron / Celgene Bristol-Myers Squibb / Merck & Co*

Indication(s): Pulmonary arterial hypertension (PAH) - Phase 3
Mechanism of Action: Transforming growth factor β (TGF-β) signaling modulator
Route of Administration: Subcutaneous
Anticipated Approval Date/Status: PDUFA March 26, 2024.
Estimated Price: $300,000–$500,000 per year.
Drug Highlights: In the STELLAR Phase 3 trial, it demonstrated an impressive increase of almost 41 meters in the 6-minute walk distance, surpassing the clinically significant threshold, and potential disease-modifying effects, presenting a promising shift from conventional vasodilatory treatments. Its subcutaneous administration every 3 weeks further adds to its appeal as an effective and convenient add-on therapy, potentially impacting the current standard of care for PAH patients.

MIN-101 (Roluperidone)
by Minerva / Mitsubishi Tanabe

Indication(s): Schizophrenia
Mechanism of Action: 5-HT2A serotonin receptor antagonist
Route of Administration: Oral
Anticipated Approval Date/Status: PDUFA of 02/26/2024
Estimated Price: $20,000-$50,000 per year
Drug Highlights: There are currently no approved drugs in the U.S. for the treatment of the negative symptoms of schizophrenia. Despite narrowly missing its primary endpoint in the Phase 3 trial, the drug demonstrated continuous improvement in negative symptoms over a year with a favorable side-effect profile, offering potential advancements in treating a significant aspect of schizophrenia, a condition with substantial disease burden.

ACT-132577 (Aprocitentan)
by Idorsia / Johnson & Johnson (Janssen)

Indication(s): Treatment-resistant hypertension
Mechanism of Action: 5 Endothelin receptor antagonist (ERA)
Route of Administration: Oral
Anticipated Approval Date/Status: PDUFA date of March 19, 2024
Estimated Price: $5,000-$10,000 per year
Drug Highlights: The PRECISION trial demonstrated significant reductions in mean systolic blood pressure, maintained up to week 48, and notable decreases in proteinuria, supporting its potential as a hypertension management option. Although approximately 30% of patients experienced mild to moderate edema/fluid retention, the overall safety profile appears favorable, and an NDA submission has been made, marking a potential advancement in addressing difficult-to-control hypertension.

Vafseo (Vadadustat)
by Akebia Therapeutics / Fresenius Kabi

Indication(s): Anemia due to kidney disease
Mechanism of Action: Hypoxia-inducible factor (HIF) stabilizer
Route of Administration: Oral
Anticipated Approval Date/Status: PDUFA date of March 27, 2024
Estimated Price: $10,000 - $20,000 per year
Drug Highlights: Its three times weekly dosing, demonstrated efficacy, and comparable safety profile position it favorably, offering a promising alternative to current standards for patients with anemia in CKD who are on dialysis.