New Drug, Generic, and Biosimilar Pipeline Report

**Q4 2024**

What follows is a summary of significant predicted forthcoming drug launches of newly approved brand drugs, generic drug, and biosimilars.

| **New Drug Pipeline** | | | | | | |
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| **GENERIC NAME** | **BRAND NAME**  (Manufacturer if drug name unavailable) | **ROUTE OF ADMINISTRATION** | **STATUS** | **ESTIMATED COST** | **THERAPEUTIC AREA** | **SPECIALTY  OR TRADITIONAL** |
| Follitropin Delta | Rekovelle | Subcutaneous\* | **Approved Jun 2024** | TBD | Endocrine: Infertility | Specialty |
| Garadacimab | (CSL Behring) | Subcutaneous | 2H2024 | $750,000 annually | Immunology | Specialty |
| Insulin icodec | (Novo Nordisk) | Subcutaneous | ~~2Q2024~~  3Q2024 | $5,000 annually | Endocrine: Diabetes | Traditional |
| Deuruxolitinib | (Concert/Sun) | Oral | **Approved**  **Jul 2024** | TBD | Dermatology: Alopecia Areata | Specialty |
| Naloxone | Orexo | Nasal\* | CRL  Jul 2024 | TBD | Addiction/Substance Abuse | Traditional |
| Nemolizumab | Mitchga | Subcutaneous | **Approved**  **Aug 2024** | $50,000 annually | Dermatology | Specialty |
| Seladelpar | Livdelzi | Oral | **Approved**  **Aug 2024** | $110,000 annually | Gastrointestinal: Primary biliary cholangitis | Specialty |
| Vorasidenib | Voranigo | Oral | **Approved**  **Aug 2024** | TBD | Cancer: Glioma | Specialty |
| Midomafetamine (MDMA) | (MAPS PBC; Lykos  Therapeutics) | Oral | CRL  Aug 2024 | $5,000-$10,000  per course | Central Nervous System: Mood Disorders | Specialty |
| Arimoclomol | Miplyffa | Oral | ~~Jun 2024~~  Sept 2024 | $500,000-  $1,000,000 | Endocrine: Niemann-Pick disease Type C | Specialty |
| Tradipitant | (Vanda Pharmaceuticals) | Oral | Sept 2024 | $10,000 per course | Gastroenterology: Nausea | Specialty |
| Xanomeline; Trospium Chloride | KarXT | Oral | Sept 2024 | $20,000-$30,000  annually | Central Nervous System: Schizophrenia | Traditional |
| Marstacimab | (Pfizer) | Subcutaneous | 4Q2024 | $500,000-$750,000 annually | Hematology | Specialty |
| Lazertinib | (YuHan) | Oral | 4Q2024 | TBD | Cancer: Non- Small Cell Lung Cancer | Specialty |
| Vicagrel | (Jiangsu Vcare Pharmatech) | Oral | 4Q2024 | $5,000-$10,000  annually | Cardiovascular: Acute Coronary Syndrome | Specialty |
| Lebrikizumab | (Eli Lilly) | Subcutaneous | ~~2H2024~~  Oct 2024 | $50,000 | Dermatology: Atopic Dermatitis | Specialty |
| Acoramidis | (BridgeBio/Eidos Therapeutics) | Oral | ~~4Q2024~~  Nov 2024 | $200,000 -  $300,000 annually | Endocrine: Metabolic | Specialty |
| Govorestat | (Applied Therapeutics) | Oral | ~~2H2024~~  Nov 2024 | TBD | Endocrine: Metabolic | Specialty |
| Inavolisib | (Roche/Genentech) | Oral | Nov 2024 | $300,000 annually | Oncology | Specialty |
| Crinecerfont | (Neurocrine Biosciences) | Oral | Dec 2024 | $100,000-$300,00 annually | Endocrinology | Specialty |
| Glepaglutide | (Zeland Pharma) | Subcutaneous | Dec 2024 | $540,000 annually | Gastrointestinal: Short Bowel Syndrome | Specialty |
| Olezarsen | (Ionis Pharma) | Subcutaneous | Dec 2024 | $300,000-$500,00 annually | Endocrinology | Specialty |
| Revumenib | (Syndax) | Oral | ~~Sept 2024~~  Dec 2024 | $300,000-$500,000 annually | Cancer: Leukemia | Specialty |
| Sotagliflozin | (Lexicon Pharmaceuticals) | Oral | Dec 2024 | $5,000-$10,000 annually | Endocrinology: Diabetes | Traditional |
| Elamipretaide | (Stealth BioTherapeutics) | Ophthalmic | Jan 2025 | $750,000-$1,000,000 annually | Central Nervous System | Specialty |
| Suzetrigine | (Vertex) | Oral | Jan 2025 | $1,000 per course | Pain Management | Traditional |
| Etripamil | Cardamyst | Nasal | Mar 2025 | $5,000 per course | Cardiovascular | Specialty |
| Alnylam | Fitusiran | Subcutaneous | Mar 2024 | $500,000-$750,000 annually | Hematology | Specialty |

| **Generic and Biosimilar Pipeline** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **DRUG NAME** | **BRAND NAME** | **ROUTE OF ADMINISTRATION** | **STATUS** | **ESTIMATED 2023 US SALES (MILLIONS)** | **THERAPEUTIC AREA** | **BIOSIMILAR  OR  TRADITIONAL** |
| Raltegravir | Isentress | Oral | 2024 | $355 | Anti-Infectives: HIV | Traditional |
| Teduglutide | Gattex | Subcutaneous | 2024 | $500 | Gastrointestinal | Biosimilar |
| Nilotinib | Tasigna | Oral | ~~Jan 2024~~ 1H2024 | $1,242 | Cancer: Leukemia | Biosimilar |
| Dasatinib | Sprycel | Oral | Sept 2024 | $$2,528 | Cancer | Biosimilar |
| Oxcarbazepine | Oxtellar XR | Oral | Sept 2024 | $230 | Central Nervous System: Epilepsy | Traditional |
| Insulin Aspart (AMP-004) | Novolog | Intravenous/Subcutaneous | 4Q2024 |  | Endocrine: Diabetes | Traditional |
| Denosumab | Prolia | Subcutaneous | Nov 2024 | $3,753 | Cancer | Biosimilar |
| Phentermine/ Topirimate | Qsymia | Oral | Dec 2024 | $51 | Endocrine: Obesity | Traditional |
| Omalizumab  (CT-P39) | Xolair | Subcutaneous | 2025 | $3,390 | Respiratory: Asthma/COPD | Biosimilar |
| Toclizumab  (Tyenne) | Actemra | Intravenous\* Subcutaneous\* | ~~2024-2025~~  Jan 2025 | $1,048 | Anti-Inflammatory | Biosimilar |
| Sebetralstat | (KalVista Pharmaceuticals) | Subcutaneous) | 1Q2025 | $200,000-$300,000 annually | Immunology | Specialty |
| Ustekinumab (Wezlana) | Stelara | Subcutaneous | Jan 2025 | $20,616 | Anti-Inflammatory | Biosimilar |
| Ustekinumab (Selarsdi) | Stelara | Subcutaneous | Feb 2025 | $20,616 | Anti-Inflammatory | Biosimilar |
| Ustekinumab (Pyzchiva) | Stelara | Subcutaneous | Feb 2025 | $20,616 | Anti-Inflammatory | Biosimilar |
| Ustekinumab  (Bmab 1200) | Stelara | Subcutaneous | Feb 2025 | $20,616 | Anti-Inflammatory | Biosimilar |
| Ustekinumab  (CT-P43) | Stelara | Subcutaneous | Mar 2025 | $20,616 | Anti-Inflammatory | Biosimilar |
| Ustekinumab (FYB202) | Stelara | Subcutaneous | Apr 2025 | $20,616 | Anti-Inflammatory | Biosimilar |
| Denosumab (Jubbonti) | Prolia | Subcutaneous | May 2025 | $3,760 | Musculoskeletal: Osteoporosis | Biosimilar |
| Denoxumab  (Wyost) | Xgeva | Subcutaneous | May 2025 | $2,061 | Cancer | Biosimilar |
| Ustekinumab  (DMB-3115) | Stelara | Subcutaneous | May 2025 | $20,616 | Anti-Inflammatory | Biosimilar |
| Lecanemab | Leqembi | Subcutaneous | 2H2025 | $20,000-$50,000 annually | Central Nervous System | Specialty |
| Ustekinumab (BAT2206) | Stelara | Subcutaneous | 2H2025 | $20,616 | Anti-Inflammatory | Biosimilar |

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\*New Formulation of an Existing Product

Source: IPD Analytics, 2024

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