

## New Drug, Generic, and Biosimilar Pipeline Report

Q1 2026

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

### New Drug Pipeline

| DRUG NAME             | BRAND NAME<br>(Manufacturer if drug name unavailable) | ROUTE OF ADMINISTRATION   | STATUS     | ESTIMATED COST               | THERAPEUTIC AREA    | BIOSIMILAR OR TRADITIONAL |
|-----------------------|---|---------------------------|------------|------------------------------|---------------------|---------------------------|
| Cytisinicline         | (Achieve Life Sciences)                               | Oral                      | June 2026  | \$1,000                      | Behavior Health     | Traditional               |
| Baxdrostat            | (AstraZeneca)   | Oral                      | Q2 2026    | \$5,000-\$10,000 annually    | Cardiology          | Traditional               |
| TRN-257               | (Tris Pharma)   | Oral                      | June 2026  | \$100,000-\$200,000 annually | Sleep               | Specialty                 |
| Tavapadon             | (Pfizer / Abbvie)                                     | Oral                      | Q3 2026    | \$10,000-\$20,000 annually   | Parkinson's Disease | Traditional               |
| Icotrokinra           | (Johnson & Johnson)                                   | Oral                      | Q3 2026    | \$50,000-\$100,000           | Dermatology         | Specialty                 |
| Imsidolimab           | (AnaptysBio; Vanda Pharmaceuticals)                   | Intravenous; Subcutaneous | 2026       | \$200,000-\$300,000 annually | Dermatology         | Specialty                 |
| Insulin Icodec        | (Novo Nordisk)  | Subcutaneous              | March 2026 | \$5,000                      | Endocrinology       | Traditional               |
| Insulin Efsitora Alfa | (Eli Lilly)   | Subcutaneous              | 2026       | \$5,000                      | Endocrinology       | Traditional               |
| Dibutepinephrine      | Anaphylm  | Sublingual                | Q1 2026    | <\$5,000 per pack            | Immunology          | Traditional               |

### Generic Pipeline

| DRUG NAME              | BRAND NAME | ROUTE OF ADMINISTRATION | STATUS / EST LOE PROB | ESTIMATED 2024 US SALES (MILLIONS) | THERAPEUTIC AREA    | BIOSIMILAR OR TRADITIONAL |
|------------------------|------------|-------------------------|-----------------------|------------------------------------|---------------------|---------------------------|
| Treprostinil           | Tyvaso     | Inhaler                 | January 2026          | 728                                | Cardiovascular      | Traditional               |
| Brivaracetam           | Briviact   | Oral                    | February 2026         | 818                                | Epilepsy            | Traditional               |
| Pomalidomide           | Pomalyst   | Oral                    | March 2026            | 3,206                              | Oncology            | Traditional               |
| Metformin; Sitagliptin | Janumet    | Oral                    | May 2026              | 1,354                              | Endocrine: Diabetes | Traditional               |
| Sitagliptin            | Januvia    | Oral                    | May 2026              | 6,397                              | Endocrine: Diabetes | Traditional               |

#### Key

Launched MM YYYY Month and year drug was launched  
 Approved MM YYYY Month and year drug was approved  
 Date Updated release date

Withdrawn  
 CRL  
 EST LOE PROB

Drug has been withdrawn from FDA approval  
 Complete Response Letter - Incomplete FDA Application  
 Estimated Loss of Exclusivity Probability based on IPD Analytics' proprietary estimate of the probability of a generic launch, based on patent analysis and knowledge of generic launches

# Biosimilar Pipeline

| DRUG NAME           | BRAND NAME | ROUTE OF ADMINISTRATION | STATUS     | ESTIMATED 2024 US SALES (MILLIONS) | THERAPEUTIC AREA | BIOSIMILAR OR TRADITIONAL |
|---------------------|------------|-------------------------|------------|------------------------------------|------------------|---------------------------|
| Golimumab           | Simponi    | Subcutaneous            | 2026       | 3,700                              | Autoimmune       | Biosimilar                |
| Tofidence SC        | Acterma    | Subcutaneous            | 2026       | 1,000                              | Autoimmune       | Biosimilar                |
| Abatacept           | Orencia    | Subcutaneous            | 2026       | 4,900                              | Autoimmune       | Biosimilar                |
| Omalizumab          | Xolair     | Subcutaneous            | 2026       | 3,900                              | Autoimmune       | Biosimilar                |
| Nintedanib          | Ofev       | Oral                    | April 2026 | 2,979                              | Pulmonology      | Biosimilar                |
| Tofacitinib Citrate | Xeljanz    | Oral                    | Q2 2026    | 4,304                              | Autoimmune       | Biosimilar                |

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\*New Formulation of an Existing Product

Source: IPD Analytics, 2025

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