



## **2023 Full Year FDA Approvals Summary**

### **BLA and NDA Approvals**

#### **A Short Report**

2024-01 v1.0

# Summary

## Introduction

1. This report compiles new NDA and BLA Drugs approved by the U.S. FDA CDER and CBER Divisions for the period January through the end of December 2023.
2. The information in the following tables was sourced from the PharmaCircle FDA Product and Pipeline & Products Intelligence modules on 2024-01-08.
3. The information presented uses FDA classifications. Where FDA product information lacked classification or other necessary information the gaps were filled in by PharmaCircle analysts experienced with the products and familiar with FDA classification procedures.
4. Application Numbers may include the letters A and T as suffixes. A refers to Accelerated Approval, while T refers to Tentative Approval.
5. Additional product information is provided in the individual PharmaCircle Product Profiles accessible through the Pipeline & Products Intelligence module and Keyword search function.
6. A detailed explanation of the FDA NDA Classification Codes (Types) is provided in the FDA Policy and Procedures document ([MAPP 5018.2](#)).
7. Contact [Customer Support](#) with questions regarding this report. Please report any errors.

## CBER BLA 351(a), NME

| Application Number | Product Name | Molecule                                       | Route     | Dosage Form                       | Company Name            | Approval Date | Indication                           |
|--------------------|--------------|--|-----------|-----------------------------------|-------------------------|---------------|--------------------------------------|
| 125771             | Altuviio     | efanesoctocog alfa                             | Injection | Lyophilized Powder For Solution   | Bioverativ Therapeutics | 2023-02-22    | Hemophilia                           |
| 125738             | Omisirge     | omidubicel-onlv                                | Injection | Suspension                        | Gamida Cell             | 2023-04-17    | Bone Marrow Transplantation          |
| 125757             | Vowst        | fecal microbiota spores,live-brpk              | Oral      | Capsule                           | Seres Therapeutics      | 2023-04-26    | Infections, Clostridioides difficile |
| 125775             | Arexvy       | Respiratory Syncytial Virus Vaccine,Adjuvanted | Injection | Lyophilized Powder For Solution   | GlaxoSmith Kline        | 2023-05-03    | Infections, RSV                      |
| 125774             | Vyjuvek      | beremagenegeperp avec-svdt                     | Topical   | Gel                               | Krystal Biotech         | 2023-05-19    | Epidermolysis Bullosa                |
| 125769/8           | Abrysvo      | Respiratory Syncytial Virus Vaccine            | Injection | Lyophilized Powder For Solution   | Pfizer                  | 2023-05-31    | Infections, RSV                      |
| 125781             | Elevidys     | delandistrogenemo xeparovvec-rokl              | Injection | Suspension                        | Sarepta Therapeutics    | 2023-06-22    | Duchenne Muscular Dystrophy          |
| 125734             | Lantidra     | donislecel-jujn                                | Injection | Suspension                        | CellTrans               | 2023-06-28    | Diabetes, Type 1                     |
| 125720             | Roctavian    | Valoctocogene roxaparvovec-rvox                | Injection | Suspension                        | BioMarin                | 2023-06-29    | Hemophilia A                         |
| 125761             | Cyfundus     | Anthrax Vaccine Adsorbed, Adjuvanted           | Injection | Suspension                        | EmergentBio Solutions   | 2023-07-20    | Infections, Anthrax                  |
| 125776             | Balfaxar     | prothrombin complex concentrate, human-lans    | Injection | Suspension                        | Octapharma              | 2023-07-21    | Coagulopathy                         |
| 125770             | Penbraya     | Meningococcal Groups A, B, C, W, and Y Vaccine | Injection | Lyophilized Powder For Suspension | Pfizer                  | 2023-10-20    | Infections, Meningitis               |
| 125777             | Ixchiq       | Chikungunya Vaccine, Live                      | Injection | Lyophilized Powder For Solution   | Valneva                 | 2023-11-09    | Infections, Chikungunya              |
| 125795             | Adzynma      | ADAMTS13, recombinant-krhn                     | Injection | Lyophilized Powder For Solution   | Takeda                  | 2023-11-09    | Thrombotic Thrombocytopenic Purpura  |

**CDER Emergency Use Authorization**

| Application Number | Product Name | Molecule    | Route     | Dosage Form | Company Name | Approval Date | Indication                      |
|--------------------|--------------|-------------|-----------|-------------|--------------|---------------|---------------------------------|
| Emergency          | Gohibic      | vilobelimab | Injection | Solution    | InflaRx      | 2023-04-04    | COVID-19 Associated Morbidities |

**CBER BLA Emergency Use Authorization**

| Application Number | Product Name   | Molecule       | Route     | Dosage Form | Company Name | Approval Date | Indication           |
|--------------------|--|----------------|-----------|-------------|--------------|---------------|----------------------|
| Emergency          | Moderna COVID-19 Vaccine (2023-2024 Formula)             | andusomeran    | Injection | Suspension  | Moderna      | 2023-09-11    | Infections, COVID-19 |
| Emergency          | Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)     | raxtozinameran | Injection | Suspension  | BioNTech     | 2023-09-11    | Infections, COVID-19 |
| Emergency          | Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) | NVX-CoV2601    | Injection | Suspension  | Novavax      | 2023-10-03    | Infections, COVID-19 |

## CDER BLA 351(a), Type 1, NME

| Application Number | Product Name | Molecule                  | Route        | Dosage Form                     | Company Name        | Approval Date | Indication                               |
|--------------------|--------------|---------------------------|--------------|---------------------------------|---------------------|---------------|--|
| 761269A            | Leqembi      | lecanemab-irnb            | Injection    | Solution                        | Eisai               | 2023-01-06    | Alzheimer's                              |
| 761278             | Lamzede      | velmanase alfa-tycv       | Injection    | Lyophilized Powder For Solution | Chiesi Farmaceutici | 2023-02-16    | Lysosomal Storage Disease                |
| 761334A            | Zynyz        | retifanlimab-dlwr         | Injection    | Solution                        | Incyte              | 2023-03-22    | Cancer, Merkel Cell Carcinoma Metastatic |
| 761161             | Elfabrio     | pegunigalsidase alfa-iwxj | Single-Use   | Solution                        | Chiesi Farmaceutici | 2023-05-09    | Fabry Disease                            |
| 761324A            | Epkinly      | epcoritamab- bysp         | Subcutaneous | Solution                        | Genmab              | 2023-05-19    | Cancer, B-Cell Lymphomas, DLBCL          |
| 761309A            | Columvi      | glofitamab-gxbr           | Injection    | Solution                        | Genentech           | 2023-06-15    | Cancer, DLBCL                            |
| 761286             | Rystiggo     | Rozanolixizumab-noli      | Subcutaneous | Solution                        | Ucb                 | 2023-06-26    | Myasthenia Gravis                        |
| 761184             | Ngenla       | somatrogon-ghla           | Injection    | Solution                        | Pfizer              | 2023-06-27    | GH Deficiency, Child                     |
| 761328             | Beyfortus    | nirsevimab-alip           | Injection    | Solution                        | Astrazeneca         | 2023-07-17    | Infections, RSV                          |
| 761342A            | Talvey       | talquetamab-tgvs          | Injection    | Solution                        | Janssen Biotech     | 2023-08-09    | Cancer, Multiple Myeloma                 |
| 761345A            | Elrexio      | elranatamab               | Injection    | Solution                        | Pfizer              | 2023-08-14    | Cancer, Multiple Myeloma                 |
| 761339             | Veopoz       | pozelimab-bbfg            | Injectable   | Solution                        | Regeneron           | 2023-08-18    | Gastrointestinal Diseases                |

**CDER BLA 351(a), Type 1, NME**

| Application Number | Product Name | Molecule                       | Route      | Dosage Form                           | Company Name           | Approval Date | Indication                              |
|--------------------|--------------|--------------------------------|------------|---------------------------------------|------------------------|---------------|---|
| 761204             | Pombiliti    | cipaglucosidase<br>alfa-atga   | Injection  | Lyophilized<br>Powder For<br>Solution | Amicus                 | 2023-09-28    | Pompe Disease                           |
| 761151             | Bimzelx      | bimekizumab-bkzx               | Injection  | Solution                              | Ucb                    | 2023-10-17    | Psoriasis                               |
| 761279             | OmvoH        | mirikizumab-mrkz               | Single-Use | Solution                              | Eli Lilly              | 2023-10-26    | Ulcerative Colitis                      |
| 761240             | Loqtorzi     | toripalimab-tpzi               | Injection  | Solution                              | Coherus<br>Biosciences | 2023-10-27    | Cancer,<br>Nasopharyngeal<br>Metastatic |
| 761134             | Ryzneuta     | efbemalenograstim<br>alfa-vuxw | Injection  | Solution                              | Evide<br>Biotechnology | 2023-11-16    | Neutropenia,<br>Cancer/Chemo-Induced    |

**CDER BLA 351(a), Type 5, New Formulation or Manufacturer**

| Application Number | Product Name | Molecule    | Route       | Dosage Form | Company Name | Approval Date | Indication         |
|--------------------|--------------|-------------|-------------|-------------|--------------|---------------|--------------------|
| 761355             | Eylea Hd     | afibercept  | Injection   | Solution    | Regeneron    | 2023-08-18    | AMD, Wet           |
| 761133             | Entyvio      | vedolizumab | Intravenous | Solution    | Takeda       | 2023-09-27    | Ulcerative Colitis |

**CDER BLA 351(a), Type 3 - New Dosage Form**

| Application Number | Product Name | Molecule    | Route     | Dosage Form | Company Name | Approval Date | Indication          |
|--------------------|--------------|-------------|-----------|-------------|--------------|---------------|---------------------|
| 761349             | Cosentyx     | secukinumab | Injection | Solution    | Novartis     | 2023-10-06    | Arthritis, Multiple |

**CDER BLA 351(a), BLA**

| Application Number | Product Name    | Molecule                                 | Route     | Dosage Form | Company Name | Approval Date | Indication        |
|--------------------|-----------------|--|-----------|-------------|--------------|---------------|-------------------|
| 761304             | Vyvgart Hytrulo | efgartigimod alfa and hyaluronidase-qvfc | Injection | Solution    | Argenx       | 2023-06-20    | Myasthenia Gravis |

**CDER BLA 351(k), Biosimilar**

| Application Number | Product Name | Molecule         | Route     | Dosage Form      | Company Name        | Approval Date | Indication                 |
|--------------------|--------------|------------------|-----------|------------------|---------------------|---------------|----------------------------|
| 761219             | Yuflyma      | adalimumab-aaty  | Injection | Solution         | Celltrion           | 2023-05-23    | Arthritis, Multiple        |
| 761322             | Tyruko       | natalizumab-sztn | Injection | Solution         | Sandoz              | 2023-08-24    | Multiple Sclerosis         |
| 761354             | Tofidence    | tocilizumab-bavi | Injection | Solution         | Biogen              | 2023-09-29    | Arthritis, Multiple        |
| 761358             | Zymfentra    | infliximab-dyyb  | Injection | PFS/Pen Solution | Celltrion           | 2023-10-20    | Inflammatory Bowel Disease |
| 761285/331         | Wezlana      | ustekinumab-auub | Injection | PFS/Pen Solution | Amgen               | 2023-10-31    | Inflammatory Bowel Disease |
| 761198             | Avzivi       | bevacizumab-tjnj | Injection | Solution         | Bio-Thera Solutions | 2023-12-06    | Cancers                    |



## CDER NDA 351(a), Type 1, NME

| Application Number | Product Name | Molecule                    | Route       | Dosage Form                     | Company Name     | Approval Date | Indication                |
|--------------------|--------------|-----------------------------|-------------|---------------------------------|------------------|---------------|---------------------------|
| 214373             | Brenzavvy    | bexagliflozin               | Oral        | Tablet                          | TheracosBio      | 2023-01-20    | Diabetes, Type 2          |
| 217639             | Orserdu      | elacestrant dihydrochloride | Oral        | Tablet                          | Stemline Therap  | 2023-01-27    | Cancer, Breast Metastatic |
| 216059A            | Jaypirca     | pirtobrutinib               | Oral        | Tablet                          | Loxo             | 2023-01-27    | Cancer, MCL, CLL          |
| 216951             | Jesduvroq    | daprodustat                 | Oral        | Tablet                          | Glaxosmith Kline | 2023-02-01    | Anemia, Dialysis          |
| 216403A            | Filspari     | sparsentan                  | Oral        | Tablet                          | Traverse         | 2023-02-17    | IgA Nephropathy           |
| 216718             | Skyclarys    | omaveloxolone               | Oral        | Capsule                         | Reata            | 2023-02-28    | Friedreich's Ataxia       |
| 216386             | Zavzpret     | zavegepant hydrochloride    | Nasal       | Spray Solution                  | Pfizer           | 2023-03-09    | Migraine                  |
| 217026             | Daybue       | trofinetide                 | Oral        | Solution                        | Acadia           | 2023-03-10    | Rett Syndrome             |
| 217417             | Rezzayo      | rezafungin acetate          | Intravenous | Lyophilized Powder For Solution | Cidara Theraps   | 2023-03-22    | Infections, Candidiasis   |
| 217759             | Joenja       | leniolisib phosphate        | Oral        | Tablet                          | Pharming         | 2023-03-24    | Primary Immunodeficiency  |
| 215887A            | Qalsody      | tofersen                    | Intrathecal | Solution                        | Biogen           | 2023-04-25    | ALS                       |

## CDER NDA 351(a), Type 1, NME

| Application Number | Product Name          | Molecule                    | Route        | Dosage Form    | Company Name    | Approval Date | Indication               |
|--------------------|-----------------------|-----------------------------|--------------|----------------|-----------------|---------------|--------------------------|
| 216578             | Veozah                | fezolinetant                | Oral         | Tablet         | Astellas        | 2023-05-12    | Menopause                |
| 216675             | Miebo                 | Perfluorohexyloctane        | Ophthalmic   | Solution       | Bausch And Lomb | 2023-05-18    | Dry Eye Syndrome         |
| 217188             | Paxlovid (Copackaged) | nirmatrelvir; ritonavir     | Oral         | Tablet         | Pfizer          | 2023-05-25    | Infections, COVID-19     |
| 216023             | Posluma               | flotufolastat f-18 gallium  | Injection    | Solution       | Blue Earth      | 2023-05-25    | Cancer Imaging, Prostate |
| 216203             | Inpefa                | sotagliflozin               | Oral         | Tablet         | Lexicon         | 2023-05-26    | Heart Failure            |
| 215830             | Litfulo               | ritlecitinib tosylate       | Oral         | Capsule (HPMC) | Pfizer          | 2023-06-23    | Alopecia                 |
| 216993             | Vanflyta              | quizartinib dihydrochloride | Oral         | Tablet         | Daiichi Sankyo  | 2023-07-20    | Cancer, AML              |
| 217603             | Xdemvy                | lotilaner                   | Ophthalmic   | Solution       | Tarsus          | 2023-07-24    | Blepharitis              |
| 217225             | Izervay               | avacincaptad pegol sodium   | Intravitreal | Solution       | Iveric Bio      | 2023-08-04    | AMD, Dry                 |
| 215559             | Sohonos               | palovarotene                | Oral         | Capsule        | Ipsen           | 2023-08-16    | Inflammation/Immune      |

## CDER NDA 351(a), Type 1, NME

| Application Number | Product Name | Molecule                    | Route        | Dosage Form                     | Company Name     | Approval Date | Indication                    |
|--------------------|--------------|-----------------------------|--------------|---------------------------------|------------------|---------------|-------------------------------|
| 217159             | Aphexda      | motixafortide acetate       | Subcutaneous | Lyophilized Powder For Solution | Biolinerx        | 2023-09-08    | Stem Cell Mobilization        |
| 216873             | Ojjaara      | mometotinib dihydrochloride | Oral         | Tablet                          | GlaxoSmith Kline | 2023-09-15    | Myelofibrosis                 |
| 021164             | Exxua        | gepirone hydrochloride      | Oral         | Tablet                          | Fabre Kramer     | 2023-09-22    | Depression                    |
| 215842             | Rivfloza     | nedosiran sodium            | Injection    | Solution                        | Novo             | 2023-09-29    | Primary Hyperoxaluria         |
| 216956             | Velsipity    | etrasimod arginine          | Oral         | Tablet                          | Pfizer           | 2023-10-12    | Ulcerative Colitis            |
| 216834             | Zilbrysq     | zilucoplan sodium           | Injection    | PFS Solution                    | Ucb              | 2023-10-17    | Myasthenia Gravis             |
| 215239             | Agamree      | vamorolone                  | Oral         | Suspension                      | Catalyst         | 2023-10-26    | Duchenne Muscular Dystrophy   |
| 217369             | Zurzuvae     | zuranolone                  | Oral         | Capsule                         | Biogen           | 2023-10-31    | Depression                    |
| 217564             | Fruzaqla     | fruquintinib                | Oral         | Capsule                         | Takeda           | 2023-11-08    | Cancer, Colorectal Metastatic |

**CDER NDA 351(a), Type 1, NME**

| Application Number | Product Name | Molecule                  | Route     | Dosage Form | Company Name | Approval Date | Indication                      |
|--------------------|--------------|---------------------------|-----------|-------------|--------------|---------------|---------------------------------|
| 218213             | Augtyro      | repotrectinib             | Oral      | Capsule     | Bristol      | 2023-11-15    | Cancer, NSCLC Metastatic        |
| 218197             | Truqap       | capivasertib              | Oral      | Tablet      | Astrazeneca  | 2023-11-16    | Cancer, Breast Metastatic       |
| 217677             | Ogsiveo      | nirogacestat hydrobromide | Oral      | Tablet      | Springworks  | 2023-11-27    | Fibromatosis                    |
| 218276             | Fabhalta     | iptacopan hydrochloride   | Oral      | Capsule     | Novartis     | 2023-12-05    | PNH                             |
| 215064             | Filsuvez     | birch triterpenes         | Topical   | Gel         | Amryt        | 2023-12-18    | Epidermolysis Bullosa           |
| 217388             | Wainua       | eplontersen sodium        | Injection | Solution    | Ionis        | 2023-12-21    | Familial Amyloid Polyneuropathy |

**CDER NDA, Type 1, 4 New Combination**

| Application Number | Product Name         | Molecule   | Route       | Dosage Form                     | Company Name    | Approval Date | Indication                      |
|--------------------|----------------------|--|-------------|---------------------------------|-----------------|---------------|---------------------------------|
| 216974             | Xacduro (Copackaged) | durlobactam sodium;<br>durlobactam sodium;<br>sulbactam sodium | Intravenous | Lyophilized Powder For Solution | Entasis Therap. | 2023-05-23    | Pneumonia                       |
| 214520             | Defencath            | heparin sodium;<br>taurolidine                                 | Injection   | Solution                        | Cormedix        | 2023-11-15    | Infections, Local Catheter Site |

**CDER NDA Type 2, New Active**

| Application Number | Product Name | Molecule            | Route | Dosage Form | Company Name | Approval Date | Indication                          |
|--------------------|--------------|---------------------|-------|-------------|--------------|---------------|-------------------------------------|
| 211566             | Zituvio      | sitagliptin         | Oral  | Tablet      | Zydus        | 2023-10-18    | Diabetes, Type 2                    |
| 216774             | Alvaiz       | eltrombopag choline | Oral  | Tablet      | Teva         | 2023-11-29    | Idiopathic Thrombocytopenic Purpura |

## CDER NDA Type 3, New Dosage Form

| Application Number | Product Name            | Molecule                                      | Route         | Dosage Form                       | Company Name     | Approval Date | Indication                               |
|--------------------|-------------------------|---|---------------|-----------------------------------|------------------|---------------|--|
| 208715T            | Cabazitaxel             | cabazitaxel                                   | Intravenous   | Solution                          | Sandoz           | 2023-01-05    | Cancer, Prostate                         |
| 212849             | Rykindo                 | risperidone                                   | Intramuscular | Lyophilized Powder For Suspension | Shandong Luye    | 2023-01-13    | Bipolar Disorder                         |
| 213260             | Atorvaliq               | atorvastatin calcium                          | Oral          | Suspension                        | Cmp              | 2023-02-01    | Angina Pectoris                          |
| 217171             | Syfovre                 | pegcetacoplan                                 | Intravitreal  | Solution                          | Apellis          | 2023-02-17    | AMD, Dry                                 |
| 205394             | Rizafilm                | rizatriptan benzoate                          | Oral          | Film                              | Gensco           | 2023-04-14    | Migraine                                 |
| 214876             | Zejula                  | niraparib tosylate                            | Oral          | Tablet                            | Glaxosmith Kline | 2023-04-26    | Cancer, Fallopian                        |
| 217660             | Trikafta (Copackaged)   | elexacaftor, ivacaftor, tezacaftor; ivacaftor | Oral          | Sachet/ Granules                  | Vertex           | 2023-04-26    | Cystic Fibrosis                          |
| 217006             | Abilify Asimtufii       | aripiprazole                                  | Intramuscular | Suspension                        | Otsuka           | 2023-04-27    | Bipolar Disorder                         |
| 216185             | Motpoly Xr              | lacosamide                                    | Oral          | Capsule                           | Aucta            | 2023-05-04    | Partial Seizure                          |
| 215721             | Zolpidem Tartrate       | zolpidem tartrate                             | Oral          | Capsule                           | Almatica         | 2023-05-09    | Insomnia                                 |
| 217470             | Opvee                   | nalmefene hydrochloride                       | Nasal         | Spray Solution                    | Indivior         | 2023-05-22    | Opioid Dependence                        |
| 210136             | Brixadi                 | buprenorphine                                 | Subcutaneous  | Solution                          | Braeburn         | 2023-05-23    | Opioid Dependence                        |
| 217110             | Melphalan Hydrochloride | melphalan hydrochloride                       | Intravenous   | Solution                          | Apotex           | 2023-08-18    | Cancer, Multiple Myeloma                 |
| 216686             | Focinvez                | fosaprepitant dimeglumine                     | Intravenous   | Solution                          | Steriscience     | 2023-08-22    | Chemotherapy-Induced Nausea and Vomiting |
| 217064             | Ryzumvi                 | phentolamine mesylate                         | Ophthalmic    | Solution                          | Ocuphire         | 2023-09-25    | Myosis Induction                         |

**CDER NDA Type 3, New Dosage Form**

| Application Number | Product Name            | Molecule                         | Route        | Dosage Form           | Company Name | Approval Date | Indication               |
|--------------------|-------------------------|----------------------------------|--------------|-----------------------|--------------|---------------|--------------------------|
| 217729             | Bosulif                 | bosutinib                        | Oral         | Capsule               | Pfizer       | 2023-09-26    | Cancer, CML              |
| 022335             | Technegas Kit           | technetium tc-99m labeled carbon | Inhalation   | Aerosol               | Cyclomedica  | 2023-09-29    | Imaging Agents           |
| 217836             | Qlosi                   | pilocarpine hydrochloride        | Ophthalmic   | Solution              | Orasis       | 2023-10-17    | Presbyopia               |
| 218550             | Rozlytrek               | entrectinib                      | Oral         | Pellet                | Genentech    | 2023-10-20    | Cancer, NSCLC Metastatic |
| 218010             | Idose Tr                | travoprost                       | Intracameral | Implant               | Glaukos      | 2023-12-13    | Ocular Hypertension      |
| 204311             | Abacavir And Lamivudine | abacavir; lamivudine             | Oral         | Tablet For Suspension | Mylan        | 2023-12-22    | Infections, HIV/AIDS     |

**CDER NDA Type 3,4, New Dosage and New Combination**

| Application Number | Product Name | Molecule    | Route   | Dosage Form | Company Name | Approval Date | Indication            |
|--------------------|--------------|-------------|---------|-------------|--------------|---------------|-----------------------|
| 217242             | Zoryve       | roflumilast | Topical | Foam        | Arcutis      | 2023-12-15    | Seborrheic Dermatitis |

## CDER NDA Type 4, New Combination

| Application Number | Product Name  | Molecule   | Route      | Dosage Form            | Company Name       | Approval Date | Indication                 |
|--------------------|---|--|------------|------------------------|--------------------|---------------|----------------------------|
| 214070             | Airsupra  | albuterol sulfate;<br>budesonide   | Inhalation | Suspension             | Astrazeneca        | 2023-01-10    | Asthma<br>Bronchospasm     |
| 214544T            | Dolutegravir;<br>Emtricitabine;<br>Tenofovir<br>Alafenamide         | dolutegravir;emtricitabine;tenofovir alafenamide   | Oral       | Tablet                 | Lupin              | 2023-01-19    | Infections,<br>HIV/AIDS    |
| 209471             | Combogesic  | acetaminophen;<br>ibuprofen  | Oral       | Tablet                 | Aft Pharms         | 2023-03-01    | Pain<br>Management         |
| 215448T            | Dolutegravir,<br>Emtricitabine<br>And Tenofovir<br>Alafenamide      | dolutegravir,<br>emtricitabine and<br>tenofovir alafenamide  | Oral       | Tablet                 | Aurobindo          | 2023-05-26    | Infections,<br>HIV/AIDS    |
| 215344             | Suflave   | magnesium sulfate;<br>polyethylene glycol 3350;<br>potassium chloride;<br>sodium chloride; sodium<br>sulfate | Oral       | Powder<br>For Solution | Braintree          | 2023-06-15    | Bowel Cleansing            |
| 211868T            | Dolutegravir;<br>Lamivudine;<br>Tenofovir<br>Disoproxil<br>Fumarate | dolutegravir;<br>lamivudine; tenofovir<br>disoproxil fumarate  | Oral       | Tablet                 | Emcure             | 2023-07-12    | Infections,<br>HIV/AIDS    |
| 215187T            | Dolutegravir;<br>Emtricitabine;<br>Tenofovir<br>Alafenamide         | dolutegravir;emtricitabine<br>;tenofovir alafenamide   | Oral       | Tablet                 | Lupin              | 2023-07-18    | Infections,<br>HIV/AIDS    |
| 216793             | Akeega  | abiraterone acetate;<br>niraparib tosylate   | Oral       | Tablet                 | Janssen<br>Biotech | 2023-08-11    | Cancer, CRPC<br>Metastatic |



**CDER NDA Type 4, New Combination**

| Application Number | Product Name                                       | Molecule   | Route          | Dosage Form                     | Company Name    | Approval Date | Indication                        |
|--------------------|--|--|----------------|---------------------------------|-----------------|---------------|-----------------------------------|
| 201848             | Hepzato  | melphalan hydrochloride                            | Intra-Arterial | Lyophilized Powder For Solution | Delcath Systems | 2023-08-14    | Cancer, Uveal Melanoma Metastatic |
| 218193T            | Abacavir; Dolutegravir; Lamivudine                 | abacavir; dolutegravir; lamivudine                 | Oral           | Tablet For Suspension           | Mylan           | 2023-08-16    | Infections, HIV/AIDS              |
| 213681T            | Dolutegravir; Emtricitabine; Tenofovir Alafenamide | dolutegravir; emtricitabine; tenofovir alafenamide | Oral           | Tablet                          | Laurus Labs     | 2023-10-12    | Infections, HIV/AIDS              |
| 216632             | Cabtreo  | adapalene; benzoyl peroxide; clindamycin phosphate | Topical        | Gel                             | Bausch          | 2023-10-20    | Acne                              |
| 209847T            | Darunavir And Ritonavir                            | darunavir and ritonavir                            | Oral           | Tablet                          | Mylan           | 2023-12-22    | Infections, HIV/AIDS              |

**CDER NDA TYPE 4/5 New Combination and New Formulation or New Manufacturer**

| Application Number | Product Name  | Molecule  | Route       | Dosage Form           | Company Name | Approval Date | Indication            |
|--------------------|---|---|-------------|-----------------------|--------------|---------------|-----------------------|
| 216903             | Preveduo  | glycopyrrolate; neostigmine methylsulfate               | Intravenous | PFS Solution          | Slayback     | 2023-02-23    | Neuromuscular Disease |
| 217514             | Tafinlar  | dabrafenib mesylate                                     | Oral        | Tablet For Suspension | Novartis     | 2023-03-16    | Cancer, Solid         |
| 217016T            | Dolutegravir; Tenofovir Disoproxil Fumarate; Lamivudine | dolutegravir; tenofovir disoproxil fumarate; lamivudine | Oral        | Tablet                | Strides      | 2023-09-14    | Infections, HIV/AIDS  |

## CDER NDA, Type 5, New Formulation or Manufacturer

| Application Number | Product Name                     | Molecule                                 | Route             | Dosage Form                       | Company Name       | Approval Date | Indication                          |
|--------------------|----------------------------------|--|-------------------|-----------------------------------|--------------------|---------------|-------------------------------------|
| 210274             | Vancomycin Hydrochloride         | vancomycin hydrochloride                 | Intravenous, Oral | Lyophilized Powder For Solution   | Zhejiang Novus     | 2023-01-20    | Bacteremia                          |
| 217415             | Daptomycin                       | daptomycin                               | Intravenous       | Lyophilized Powder For Solution   | Xellia Pharms      | 2023-01-30    | Bacteremia                          |
| 216820             | Technetium Tc 99m Mertiatide Kit | technetium tc-99m mertiatide kit         | Intravenous       | Lyophilized Powder For Solution   | Jubilant Draximage | 2023-01-30    | Imaging Agents                      |
| 215870             | Fentanyl Citrate                 | fentanyl citrate                         | Intravenous       | Solution                          | Exela Pharma       | 2023-02-08    | Anesthesia Induction<br>Anesthesia, |
| 208969             | Rextovy                          | naloxone hydrochloride                   | Nasal             | Spray                             | Amphastar          | 2023-03-07    | Opioid Dependence                   |
| 217513             | Mekinist                         | trametinib dimethyl sulfoxide            | Oral              | Powder For Solution               | Novartis           | 2023-03-16    | Cancer, Glioma                      |
| 215875             | Adrenalin                        | epinephrine                              | Intravenous       | Solution                          | Par Sterile        | 2023-04-21    | Hypotension                         |
| 213586             | Uzedy                            | risperidone                              | Subcutaneous      | Suspension                        | Teva               | 2023-04-28    | Schizophrenia                       |
| 214952             | Liqrev                           | sildenafil citrate                       | Oral              | Suspension                        | Cmp Dev            | 2023-04-28    | Pulmonary Arterial Hypertension     |
| 215319             | Dolutegravir                     | dolutegravir                             | Oral              | Oral Film                         | Laurus             | 2023-04-28    | Infections, HIV/AIDS                |
| 215352             | Mydcombi                         | phenylephrine hydrochloride; tropicamide | Ophthalmic        | Solution                          | Eyenovia           | 2023-05-05    | Mydriasis Induction                 |
| 211413             | Cefazolin Sodium                 | cefazolin sodium                         | Intravenous       | Lyophilized Powder For Solution   | Hq SpcIt Pharma    | 2023-05-08    | Infections                          |
| 215179             | Pemetrexed                       | pemetrexed disodium                      | Intravenous       | Solution                          | Shilpa             | 2023-05-22    | Cancer, Mesothelioma                |
| 216338             | Paclitaxel                       | paclitaxel                               | Intravenous       | Lyophilized Powder For Suspension | Teva               | 2023-05-11    | Cancer, Breast Metastatic           |
| 217469             | Vevye                            | cyclosporine                             | Ophthalmic        | Solution                          | Harrow Eye         | 2023-05-30    | Dry Eye Syndrome                    |

## CDER NDA, Type 5, New Formulation or Manufacturer

| Application Number | Product Name                        | Molecule                             | Route       | Dosage Form           | Company Name    | Approval Date | Indication                        |
|--------------------|-------------------------------------|--------------------------------------|-------------|-----------------------|-----------------|---------------|-----------------------------------|
| 210852             | Cyclophosphamide                    | cyclophosphamide                     | Intravenous | Solution              | Dr Reddys       | 2023-06-07    | Cancer                            |
| 215727             | Lodoco                              | colchicine                           | Oral        | Tablet                | Agepha          | 2023-06-16    | Cardiovascular Diseases           |
| 217651             | Cyclophosphamide                    | clophosphamide                       | Intravenous | Solution              | Nevakar         | 2023-06-28    | Cancer                            |
| 212905             | Ycanth                              | cantharidin                          | Topical     | Solution              | Verrica         | 2023-07-21    | Infections, Molluscum Contagiosum |
| 215212             | Meropenem                           | meropenem                            | Intravenous | Powder For Solution   | Hq Spclt Pharma | 2023-07-26    | Infections, Meningitis            |
| 217070T            | Abacavir; Dolutegravir; Lamivudine  | abacavir; dolutegravir; lamivudine   | Oral        | Tablet For Suspension | Aurobindo       | 2023-08-14    | Infections, HIV/AIDS              |
| 217150             | Cyclophosphamide                    | cyclophosphamide                     | Intravenous | Solution              | Sandoz          | 2023-09-12    | Cancers                           |
| 216755             | Likmez                              | metronidazole                        | Oral        | Suspension            | Saptalis        | 2023-09-22    | Infections, Multiple              |
| 215211             | Opfolda                             | miglustat                            | Oral        | Capsule               | Amicus          | 2023-09-28    | Pompe Disease                     |
| 217569             | Vasopressin In Sodium Chloride 0.9% | vasopressin                          | Intravenous | Solution              | Baxter          | 2023-09-29    | Blood Disorders                   |
| 216142             | Micafungin In Sodium Chloride 0.9%  | micafungin sodium                    | Intravenous | Solution              | Baxter          | 2023-09-29    | Abscess Infections, Candidiasis   |
| 215320             | Combogesic Iv                       | acetaminophen and ibuprofen          | Injection   | Solution              | Hikma           | 2023-10-17    | Post-Operative Pain               |
| 216743             | Zituvimet                           | metformin hydrochloride; sitagliptin | Oral        | Tablet                | Zydus           | 2023-11-03    | Diabetes, Type 2                  |
| 216099             | Phyrago                             | dasatinib                            | Oral        | Tablet                | Nanocopoeia     | 2023-12-05    | Cancer, CLL, CML                  |
| 217812             | Hydromorphone Hydrochloride         | hydromorphone hydrochloride          | Injection   | Solution              | Hikma           | 2023-12-14    | Pain Management                   |

**CDER NDA Type 5, New Formulation or Manufacturer And Type 8, Partial Rx to OTC Switch**

| Application Number | Product Name | Molecule               | Route | Dosage Form | Company Name   | Approval Date | Indication        |
|--------------------|--------------|------------------------|-------|-------------|----------------|---------------|-------------------|
| 217722             | Rivive       | naloxone hydrochloride | Nasal | Spray       | Harm Reduction | 2023-07-28    | Opioid Dependence |

**CDER NDA Type 10, New Indication as Distinct NDA**

| Application Number | Product Name | Molecule                | Route        | Dosage Form | Company Name | Approval Date | Indication          |
|--------------------|--------------|-------------------------|--------------|-------------|--------------|---------------|---------------------|
| 213931             | Xphozah      | Tenapanor hydrochloride | Oral         | Tablet      | Ardelyx      | 2023-10-17    | Hyperphosphatemia   |
| 215151             | Voquezna     | vonoprazan fumarate     | Oral         | Tablet      | Phathom      | 2023-11-01    | H. pylori Infection |
| 217806             | Zepbound     | tirzepatide             | Subcutaneous | Solution    | Eli Lilly    | 2023-11-08    | Diabetes, Type 2    |

**CDER NDA Approvals, Other Type or Unknown**

| Application Number | Product Name                      | Molecule                        | Route      | Dosage Form                      | Company Name | Approval Date | Indication                                |
|--------------------|-----------------------------------|---------------------------------|------------|----------------------------------|--------------|---------------|---|
| 216354             | Austedo Xr <sup>1</sup>           | deutetrabenazine                | ORAL       | Tablet, Extended Release         | Teva         | 2023-02-17    | Dyskinesia                                |
| 216579             | Symbicort Aerosphere <sup>2</sup> | budesonide; formoterol fumarate | Inhalation | Aerosol, Metered                 | Astrazeneca  | 2023-04-28    | COPD                                      |
| 214755             | Lumryz <sup>1</sup>               | sodium oxybate                  | ORAL       | For Suspension, Extended Release | Avadel       | 2023-05-01    | Sleep Disorders                           |
| 217581             | Xalkori <sup>1</sup>              | crizotinib                      | Oral       | Capsule, Pellets                 | Pfizer       | 2023-09-07    | Cancer, ALCL<br>NSCL, Soft Tissue Sarcoma |
| 217927             | Coxanto <sup>1</sup>              | oxaprozin                       | ORAL       | Capsule                          | Solubiomix   | 2023-10-20    | Rheumatoid Arthritis                      |
| 215500             | Iwifin <sup>1</sup>               | eflornithine hydrochloride      | ORAL       | Tablet                           | US WorldMeds | 2023-12-13    | Cancer, Neuroblastoma                     |

1- Unknown

2- Efficacy

# 2023 Full Year FDA Approvals Summary

## BLA and NDA Approvals

### A Short Report

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