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# 1ST QUARTER 2020
# PIPELINE REPORT

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**Look for these Drug Pipeline Reports each quarter.**

## PIPELINE HIGHLIGHTS:

### Recent Approvals

- **Trikafta (elexacaftor (VX-445) + tezacaftor + ivacaftor) -** Cystic fibrosis. Approved 10/21/19
- **Vumerity (diroximel fumarate)-** Relapsing forms of multiple sclerosis (MS). Approved 10/29/19
- **Brukinsa (zanubrutinib) –** Blood-borne cancer (mantle cell lymphoma). Approved 11/14/19
- **Givlaari (givosiran) –** Acute hepatic porphyria. Approved 11/20/19
- **Jynneos (smallpox vaccine) –** Prevention of smallpox and monkeypox. Approved 9/24/19
- **Reblozyl (luspatercept) –** Anemia (beta thalassemia). Approved 11/8/19
- **Rybelsus (semaglutide) –** Diabetes, types 1 and 2. Approved 9/20/19
- **Scenesse (afamelanotide) –** Rare, serious skin condition (erythropoietic protoporphyria). Approved 10/8/19
- **Oxbryta (voxelotor) –** Sickle cell disease. Approved 11/25/19
- **Adakveo (crizanlizumab-tmca) –** Sickle cell disease. Approved 11/15/19

### Anticipated FDA Approvals

- **Palforzia, aka AR101 –** Peanut allergy. Expected FDA decision: 1/2020
- **RVT-802 -** Primary immune deficiency resulting from congenital athymia. Expected FDA decision: 12/2019
- **Enfortumab vedotin, aka ASG-22ME –** Cancer of the urinary tract (urothelial cancer). Expected FDA decision: 3/15/2020
- **Avapritinib, aka BLU-285 –** Cancer of the GI tract: gastrointestinal stromal tumors (GIST). Expected FDA decision: 2/14/2020
- **Teprotumumab –** Thyroid eye disease: Graves' orbitopathy. Expected FDA decision: 3/8/2020
- **Exenatide implant –** Diabetes: type 2. Expected FDA decision: 3/9/2020
- **Tazemetostat –** Cancer: Epithelioid sarcoma. Expected FDA decision: 1/23/2020
- **Ebola vaccine, aka V920 and rVSV-ZEBOV-GP –** Prevention of Ebola. Expected FDA decision: 3/14/2020

## PIPELINE HIGHLIGHTS: *(continued)*

### Market Launched Biosimilar Approvals

- **Ogivri (trastuzumab-dkst) –** Biosimilar for reference product Herceptin – Launched 12/2/19
- **Ziextenzo (pegfilgrastim) –** Biosimilar for reference product Neulasta – Launched December 2019

### Anticipated Biosimilars FDA Launch Dates

- **Avsola (infliximab-axxq) –** reference product Remicade – FDA approved 12/6/19; Anticipated launch date December 2019
- **Zirabev (bevacizumab-bvzr) –** reference product Avastin -- FDA Approved 6/2019; Anticipated Launch Date Q4 2019
- **Biosimilars for reference product Rituxan, anticipated Launch Date Q3-4 2019**
  - **Truxima (rituximab-abbs) –** FDA Approved 11/2018
  - **Ruxience (rituximab-pvvr) –** FDA Approved 7/2019
- **Biosimilars for reference product Herceptin, anticipated Launch Date 12/2019**
  - **Herzuma (trastuzumab-pkrb) –** FDA Approved 12/2018
  - **Ontruzant (trastuzumab-dttb) –** FDA Approved 1/2019
  - **Trazimera (trastuzumab-qyyp) –** FDA Approved 3/2019

## Recent FDA Approvals

| Approval Date | Estimated WAC / Year & Benefit coverage | Drug Name / Manufacturer | Treatment Indication | Disease or Administration Comments | Clinical Comments | Therapy Options Approximate WAC/Year |
|---|---|---|---|---|---|---|
| 11/15/2019 | **$85,000-115,000**<br><br>**Medical Benefit** | **Brand Name**<br>**Adakveo**<br>crizanlizumab-tmca<br><br>Novartis | **Blood condition:**<br>sickle cell disease (SCD) | IV every 2 weeks for 2 weeks then every 4 weeks.<br><br>In sickle cell disease, deformed red blood cells clog blood vessels, causing severe pain and life-threatening complications.<br><br>About 100,000 people in the US have sickle cell disease.<br><br>Granted breakthrough therapy designation by FDA on 1/8/2019. | **Mechanism:** Blocks adhesion of sickled cells. | **Therapy Options:**<br>Hydroxyurea<br>› Siklos: $54,750<br>› Droxia: $2774<br>› Generic: $2584<br>Endari (L-glutamine): $40,515<br>Hematopoietic cell transplant: $350,000 to $800,000 |

## Recent FDA Approvals *(continued)*

| Approval Date | Estimated WAC / Year & Benefit coverage | Drug Name / Manufacturer | Treatment Indication | Disease or Administration Comments | Clinical Comments | Therapy Options Approximate WAC/Year |
|---|---|---|---|---|---|---|
| 11/14/2019 | **$157,373.40**<br><br>**Phrmacy Benefit** | **Brand name**<br>**Brukinsa**<br>zanubrutinib<br><br>BeiGene | **Blood-borne cancer:** Mantle cell lymphoma (MCL) | Given orally<br><br>Incidence of MCL increases with age; expect increasing prevalence with aging population.<br><br>Was granted Priority review, Orphan Drug, and Breakthrough Therapy Designations for the treatment of MCL. | **Mechanism:** Bruton's tyrosine kinase (BTK) inhibitor | **Therapy Options:**<br>› Imbruvica $209,820<br>› Calquence $171,108<br>› Revlimid $181,392<br>› Velcade $68,400 |
| 11/20/2019 | **$575,000**<br><br>**Medical Benefit** | **Brand name**<br>**Givlaari**<br>givosiran<br><br>Alnylam | **Acute hepatic porphyria (AHP)** | Given subcutaneously, but may cause severe allergic reaction so given in a medical facility<br><br>Was granted Priority review, Orphan Drug, and Breakthrough Therapy Designations | **Mechanism:** Antisense oligonucleotide | **Therapy Options:**<br>› None (symptomatic only) |
| 09/24/2019 | **TBD upon launch**<br><br>**Medical Benefit** | **Brand name**<br>**Jynneos**<br>smallpox vaccine<br><br>Bavarian Nordic | **Vaccine to prevent Smallpox, Monkeypox** | Two doses given subcutaneously, 4 weeks apart.<br><br>Produced using modified form of vaccinia virus, which cannot reproduce in humans. Does not contain smallpox or monkeypox virus or virus particles.<br><br>This is the only available vaccine for monkeypox, which does not occur naturally in the US and is rare globally. | As smallpox was declared globally eradicated in 1980, vaccination for it is not routine. However, smallpox is considered a potential bioterrorism threat, and Jynneos will be available to persons deemed to be at risk for smallpox or monkeypox. It is also part of the US Strategic National Stockpile. | **Therapy Options:**<br>› ACAM2000, a smallpox-only vaccine available only through the federal government, produced from vaccinia virus able to replicate in humans (thus having potential to cause more side effects and spread vaccinia infection to others). |

## Recent FDA Approvals *(continued)*

| Approval Date | Estimated WAC / Year & Benefit coverage | Drug Name / Manufacturer | Treatment Indication | Disease or Administration Comments | Clinical Comments | Therapy Options Approximate WAC/Year |
|---|---|---|---|---|---|---|
| 11/25/2019 | **$125,000**<br><br>**Pharmacy Benefit** | **Brand name**<br>**Oxbryta**<br>voxelotor<br><br>Global Blood Therapeutics | **Blood condition:** sickle cell disease (SCD) | Oral<br>In sickle cell disease, deformed red blood cells clog blood vessels, causing severe pain and life-threatening complications.<br><br>About 100,000 people in the US have sickle cell disease.<br><br>Accelerated approval; was granted fast track, breakthrough, and orphan drug designation. | **Mechanism:** prevents red blood cells from taking on the "sickle" shape that causes blood vessel blockage. | **Therapy Options:**<br>Hydroxyurea<br>› Siklos: $54,750<br>› Droxia: $2774<br>› Generic: $2584<br>Endari (L-glutamine): $40,515<br>Hematopoietic cell transplant: $350,000 to $800,000 |
| 11/08/2019 | **$175,000**<br><br>**Medical Benefit** | **Brand name**<br>**Reblozyl**<br>luspatercept-aamt<br><br>Celgene Acceleron | **Anemia**<br>Beta thalassemia, transfusion dependent | Subcutaneous, every 3 weeks.<br><br>The incidence of symptomatic cases of beta thalassemia is estimated to be approximately 1 in 100,000 individuals in the general population.<br><br>Was granted Fast Track and Orphan Drug Designations | Erythroid maturation agent.<br><br>Reduces but does not eliminate the need for transfusions. | **Therapy Options:**<br>› Transfusions; annual cost $40-$100,000 |
| 9/20/2019 | **$9399**<br><br>**Pharmacy benefit** | **Brand name**<br>**Rybelsus**<br>semaglutide<br><br>Novo Nordisk Emisphere | **Diabetes:** Improve glycemic control in type 1 and/or type 2 diabetes | Oral<br><br>First drug in this class available as oral dosage form. | Glucagon-like peptide-1 (GLP-1) agonist | **Therapy Options:**<br>Other GLP-1 agonists (all administered by subcutaneous injection):<br>› Bydureon<br>› Tanzeum<br>› Trulicity<br>› Victoza<br>› Byetta<br>› Adlyxin<br>All about $5,400 per year of therapy. |

## Recent FDA Approvals *(continued)*

| Approval Date | Estimated WAC / Year & Benefit coverage | Drug Name / Manufacturer | Treatment Indication | Disease or Administration Comments | Clinical Comments | Therapy Options Approximate WAC/ Year |
|---|---|---|---|---|---|---|
| 10/08/2019 | **$50,000-100,000**<br><br>**Medical benefit** | **Brand name**<br>**Scenesse**<br>afamelanotide<br><br>Clinuvel | **Rare, serious skin condition:** Erythropoietic protoporphyria (EPP) | Implant, every 2 months.<br><br>EPP causes itching, burning, and scarring on skin exposed to sunlight. Incidence in the US is not clearly defined but in Europe approximates 1:140,000 people.<br><br>Was granted priority review and orphan drug designation by the FDA | Alpha-melanocyte stimulating hormone (alpha-MSH) analog<br><br>Scenesse allows EPP patients to tolerate increased exposure to sunlight. | **Therapy Options:**<br>› No alternatives. |
| 10/21/2019 | **$311,000**<br><br>**Pharmacy benefit** | **Brand name**<br>**Trikafta**<br>elexacaftor/ ivacaftor/ tezacaftor<br>(aka VX-445/TEZ/ IVA)<br><br>Vertex | **Cystic fibrosis (CF)** | Oral<br><br>CF is a rare, life-shortening disease caused by one or more of 2000 CFTR gene mutations. The mutated genes produce defective proteins, which lead to a buildup of mucus in the lungs, causing chronic infections and progressive damage.<br><br>The FDA granted the application for Trikafta priority review, in addition to fast track and breakthrough therapy designations. Trikafta also received orphan drug designation | **Mechanism:** Corrects the genetic defect resulting in the defective protein, and helps the healthy proteins to function.<br><br>Treats the largest group of CF patients who remain without a treatment for the underlying cause of their disease. | **Therapy Options:**<br>› Kalydeco (ivacaftor) ($427/ tab, q12h) $311,710<br>› Symdeko (tezacaftor, ivacaftor) (400/tab, qd) $146,000<br>› Orkambi (lumacaftor, ivacaftor) (187/tab, 4 per day) $273,000<br>(none has the exact same indications as Trikafta) |
| 10/29/2019 | **$87,994**<br><br>**Pharmacy benefit** | **Brand name**<br>**Vumerity**<br>diroximel fumarate<br><br>Biogen<br>Alkermes | **Multiple Sclerosis,** relapsing forms including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease | Oral, taken twice daily<br><br>Should not be taken with high-fat, high calorie food or alcohol. | Is converted in the body into dimethyl fumarate, as is Tecfidera; may cause fewer gastrointestinal problems compared to Tecfidera. | **Therapy Options:**<br>› Tecfidera $94,994 |

## Recent FDA Approvals *(continued)*

| Approval Date | Estimated WAC / Year & Benefit coverage | Drug Name / Manufacturer | Treatment Indication | Disease or Administration Comments | Clinical Comments | Therapy Options Approximate WAC/ Year |
|---|---|---|---|---|---|---|
| 12/12/2019 | **$300,000**<br><br>**Medical benefit** | **Brand name Vyondys 53**<br>golodirsen (aka SRP-4053)<br><br>Sarepta Therapeutics | **Duchenne Muscular Dystrophy (DMD)** in patients with mutation amenable to exon 53 skipping | IV<br><br>DMD is a fatal genetic neuromuscular disorder affecting one in 3,500 - 5,000 males born worldwide.<br><br>Golodirsen targets DMD with a specific genetic mutation that affects about 8% of DMD patients. It is not curative but may delay worsening of symptoms. | FDA had previously rejected this product due to concerns about possible kidney damage.<br><br>Was granted accelerated approval and priority review status by FDA; however, FDA is requiring a post-marketing confirmatory trial for continuing approval.<br><br>Emflaza is similar to prednisone (possibly with fewer side effects) in that it improves symptoms of DMD, while Vyondys 53 and Exondys 51 work more directly to address the underlying disease process. | **Therapy Options:**<br>› Exondys 51(eteplirsen) $300,000 note: indicated for patients with a DIFFERENT genetic mutation than Vyondys 53)<br>› Emflaza (deflazacort) $185,000 (oral)<br>› Prednisone generic, $115-$1000 |

## Anticipated FDA Approvals

| Expected FDA Review Date | Drug Name / Manufacturer | Indication | Disease or Administration Comments | Clinical Comments | Therapy Options |
|---|---|---|---|---|---|
| 3/15/2020 | **Brand Name TBD**<br>(enfortumab vedotin; aka ASG-22ME)<br><br>Seattle Genetics<br>Astellas | **Cancer of the urinary tract:**<br>*Urothelial cancer* | IV<br><br>May be a breakthrough for resistant urothelial cancer, which progresses in 75-80% of patients even after treatment with currently preferred agents | Monoclonal antibody/ drug conjugate that targets specific tumor cells. | **Therapy Options:**<br>› Immune checkpoint inhibitors such as pembrolizumab, atezolizumab, durvalumab, nivolumab or avelumab |

## Anticipated FDA Approvals *(continued)*

| Expected FDA Review Date | Drug Name / Manufacturer | Indication | Disease or Administration Comments | Clinical Comments | Therapy Options |
|---|---|---|---|---|---|
| 2/14/2020 | **Brand Name TBD**<br>(avapritinib; aka BLU-285)<br>Blueprint Medicines | **Cancer of the GI tract:** gastrointestinal stromal tumors (GIST) | Oral<br>FDA granted Priority Review status and Breakthrough Therapy Designation for the treatment of patients with GIST having certain cell mutations. | Selectively targets molecules that drive tumor growth.<br>No currently available treatment for the cell mutation that avapritinib targets; this type of GIST progresses within 3-4 months after preferred treatment for metastatic disease. | **Therapy Options:**<br>› imatinib, sunitinib and regorafenib |
| 6/2020 | **Brand Name TBD**<br>(sacituzumab govitecan-hziy ; aka IMMU-132)<br>Immunomedics | **Breast cancer:** Refractory, metastatic hormone receptor triple negative | IV<br>This subtype of breast cancer has very low response rate and short survival time following standard therapy; the survival rate has not improved in the last 20 years. | Monoclonal antibody/ drug conjugate that targets specific tumor cells. | **Therapy Options:**<br>› Cyclophosphamide/ doxorubicin + paclitaxel<br>› Cyclophosphamide/ docetaxel |
| 5/30/2020 | **Brand Name TBD**<br>(pemigatinib, aka INCB054828)<br>Incyte | **Gall bladder cancer:** cancer of the bile ducts | Oral<br>Rare cancer often diagnosed at an advanced stage. | Targets a protein (fibroblast growth factor) that can cause cancer if not regulated properly in the body.<br>This would be the first targeted therapy for this type of cancer. | **Therapy Options:**<br>› Surgery |
| 6/2020 | **Brand Name TBD**<br>(inebilizumab)<br>AstraZeneca<br>MedImmune<br>Viela | Nerve disease: Neuromyelitis optica spectrum disorder, NMOSD) | IV<br>Rare, autoimmune condition that causes life-threatening symptoms such as paralysis and loss of bowel and bladder function; can also cause blindness.<br>Orphan drug; FDA granted Breakthrough Therapy designation. | Monoclonal antibody that depletes the overabundance of immune cells which contributes to this condition.<br>Second product approved for this indication in 2019 (Soliris was approved in June 2019). Prior to that, treatments were symptomatic only. | **Therapy Options:**<br>› Soliris (eculizumab) |
| 4/30/2020 | **Brand Name TBD**<br>(isatuximab, aka SAR650984)<br>Sanofi<br>ImmunoGen | **Blood cancer:** Relapsed, refractory multiple myeloma | IV<br>Multiple myeloma relapses repeatedly, making it essentially incurable.<br>Orphan drug | Monoclonal antibody that targets a relatively unique feature of myeloma cells, causing them to die and also activating the immune system to kill these cells. | **Therapy options:**<br>› Lenalidomide/ dexamethasone with or without bortezomib, daratumumab, carfilzomib or ixazomib |

## Anticipated FDA Approvals *(continued)*

| Expected FDA Review Date | Drug Name / Manufacturer | Indication | Disease or Administration Comments | Clinical Comments | Therapy Options |
|---|---|---|---|---|---|
| 3/8/2020 | **Brand Name TBD**<br>(teprotumumab)<br><br>Horizon Pharma<br>Roche<br>Genmab | **Thyroid eye disease:** Graves' orbitopathy | IV<br><br>In people with hyperthyroidism, thyroid eye disease causes the eyes to "bulge out" and/or double vision. There is currently no good treatment for this.<br><br>Granted Fast Track designation, Orphan Drug Designation and Breakthrough Therapy Designation. | Prevents the antibodies causing the condition from attaching to the cells they attack. | **Therapy Options:**<br>› None |
| 3/9/2020 | **Brand Name TBD**<br>(exenatide, aka ITCA 650)<br><br>Intarcia Therapeutics | **Diabetes:** type 2 | Implant | Exenatide has been used in treating type 2 diabetes since 2011, but must be injected at least weekly (brand names Byetta and Bydureon).<br><br>Only needs to be implanted once per year. | **Therapy options:**<br>› Standard treatment for type 2 diabetes. |
| 5/24/2020 | **Brand Name TBD**<br>(risdiplam, aka RG7916)<br><br>Roche<br>Genentech<br>PTC Therapeutics | **Neuromuscular condition**<br>Spinal muscular atrophy (SMA), types 1, 2 or 3. | Oral liquid<br><br>Before Spinraza (pre-12/2016), SMA was usually fatal within 2 years. In May 2019, a one-time potentially curative gene therapy, Zolgensma, was approved.<br><br>Orphan drug, Fast Track, Priority Review designations | Like Spinraza, risdiplam acts by increasing the number of SMN2 genes available for making normal SMN (a protein necessary for functioning nerve cells). SMN is primarily made by the SMN1 gene, but in SMA patients, SMN1 is defective.<br><br>If approved, risdiplam will be the only SMA treatment that does not require administration by a healthcare professional. | **Therapy Options:**<br>› Spinraza (nusinersen), approved for all 4 types of SMA<br>› Zolgensma (onasemnogene abeparvovec-xioi), approved only for type 1 SMA |
| 1/23/2020 | **Brand Name TBD**<br>(tazemetostat)<br><br>Epizyme | **Cancer:** Epithelioid sarcoma | Oral<br><br>Orphan drug, priority review | Decreases tumor cell proliferation by Inhibiting an enzyme that is too abundant or is defective in many types of cancer.<br><br>First drug in its class; being tested for many types of cancer. | **Therapy Options:**<br>› Single-agent or combination chemotherapy |

## Anticipated FDA Approvals *(continued)*

| Expected FDA Review Date | Drug Name / Manufacturer | Indication | Disease or Administration Comments | Clinical Comments | Therapy Options |
|---|---|---|---|---|---|
| 3/14/2020 | **Brand name TBD**<br>(ebola vaccine, aka V920 and rVSV-ZEBOV-GP)<br>Merck & Co<br>NewLink Genetics | **Prevention of ebola** | Intramuscular<br>Ebola is highly contagious and often fatal.<br>As of July 2019, the Congo is experiencing the second-deadliest Ebola outbreak recorded; 1625 dead and outbreak is ongoing. | Has been available as of August 2019 to health-care workers on a "compassionate use" basis; found to 97.5% effective for those vaccinated vs. those not vaccinated. | **Therapy Options:**<br>› None |
| 12/2019 | **Brand name, generic name TBD**<br>RVT-802<br>Enzyvant Roivant | **Primary immunodeficiency**<br>(complete DiGeorge Syndrome, cDGS) | Comprised of specially-treated cells that are implanted into muscle; the result is production of functioning immune cells.<br>cDGS is a rare pediatric condition, uniformly fatal if untreated (usually within 2 years due to infection) | Tissue-based regenerative therapy<br>Granted by FDA:<br>› Breakthrough therapy designation<br>› Regenerative Medicine Advanced Therapy (RMAT) designation, a component of the 21st Century Cures Act, reserved for cell therapies, therapeutic tissue engineering products, and human cell and tissue products intended to mitigate serious or life-threatening conditions<br>› Orphan, Priority Review, Rare Pediatric Disease | **Therapy Options:**<br>› Thymic or hematopoietic cell transplantation (HCT) |
| 1/2020 | **Brand name, TBD**<br>(palforzia, aka AR101)<br>Aimmune | **Peanut allergy** | Oral powder<br>Peanut allergy is common in children, with an incidence of approximately 1.4-4.5% | Uses gradually increasing doses of peanut protein to desensitize patients.<br>ICER evaluation predicted cost-effectiveness if priced as expected, and concluded that evidence for improved outcomes with AR101 compared to peanut avoidance alone was promising but inconclusive. | **Therapy Options:**<br>› Peanut avoidance<br>› Viaskin (transdermal patch currently in development) |

## Anticipated FDA Approvals *(continued)*

| Expected FDA Review Date | Drug Name / Manufacturer | Indication | Disease or Administration Comments | Clinical Comments | Therapy Options |
|---|---|---|---|---|---|
| CRL* issued on 03/22/2019 | **Brand name Zynquista**<br>sotagliflozin<br><br>Lexicon Phamaceuticals; | **Diabetes:**<br>For patients with type 1 diabetes who lack adequate blood sugar control on insulin therapy. | Oral<br><br>Used along with insulin | Diabetic ketoacidosis, a serious diabetes complication, was more frequent in those given sotagliflozin compared to insulin alone.<br><br>In January 2019, the FDA Advisory Committee were evenly divided on whether benefits of Zynquista outweighed risks.<br><br>Received approval in Europe 8/9/2019. On July 26, 2019, Sanofi announced discontinuation of their collaboration with Lexicon in developing Zynquista following release of results from 3 clinical trials. | **Therapy Options:**<br>› Insulin |

*CRL (Complete Response Letter) is a communication to a drug's manufacturer from the FDA indicating that the application for the drug cannot be approved in its present form.

## Biosimilar Pipeline

| Approval Date | Launch Date | Biosimilar Name | Biosimilar WAC / Year Cost | Reference Product | Reference Product WAC / Year Cost | Disease Category* |
|---|---|---|---|---|---|---|
| September 2017 | July 2019 | Mvasi **<br>(bevacizumab-awwb)<br><br>Amgen<br>Allergan | $123,286.80 | Avastin (bevacizumab) | $144,872<br>(dosing at 10mg/kg q2wks) | **Cancer:** Treatment of Metastatic colorectal cancer, Non-squamous non-small cell lung cancer, Glioblastoma, Metastatic renal cell carcinoma, Persistent, recurrent, or metastatic carcinoma of the cervix |
| Expected FDA Review Q4 2020 | TBD | SB-8<br><br>Merck | TBD upon Launch | | | |
| June 2019 | Anticipated 4Q 2019 | Zirabev<br>(bevacizumab-bvzr)<br><br>Pfizer | TBD upon Launch | | | |

## Biosimilar Pipeline *(continued)*

| Approval Date | Launch Date | Biosimilar Name | Biosimilar WAC / Year Cost | Reference Product | Reference Product WAC / Year Cost | Disease Category* |
|---|---|---|---|---|---|---|
| August 2016 | Anticipated 2020-2029 | Erelzi® (etanercept-szzs)<br><br>Sandoz | TBD Upon Launch | Enbrel (etanercept) | $64,629 | **Immunosuppressant:** Ankylosing spondylitis, Juvenile idiopathic arthritis (2 years or older), Plaque psoriasis adult, Psoriatic arthritis, Rheumatoid arthritis |
| April 2019 | Anticipated 2020-2029 | Eticovo (etanercept-ykro)<br><br>Samsung Bioepis | TBD Upon Launch | | | |
| May 2018 | June 2018 | Retacrit™** (epoetin alfa-epbx)<br><br>Hospira<br>Pfizer<br>Vifor Pharma | $154 | Epogen<br>Procrit<br>(Epoetin Alfa) | Epogen - $232<br>Procrit - $360 | **Hematopoietic:** Treatment of anemia due to chronic kidney disease, Zidovudine in HIV-infected patients, chemotherapy in cancer patients, and reduction of allogeneic red blood cell transfusion in patients' elective surgery |
| December 2017 | 12/2/2019 | Ogivri ** (trastuzumab-dkst)<br><br>Mylan<br>Biocon | $192,244 | Herceptin (trastuzumab) | $226,895.76 (dosing at 6mg/kg/wk) | **Cancer:** Treatment of Human Epidermal growth factor Receptor 2 (HER2) adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer |
| December 2018 | Anticipated December 2019 | Herzuma (trastuzumab-pkrb)<br><br>Nippon Kayaku<br>Celltrion<br>Teva | TBD Upon Launch | | | |
| January 2019 | Anticipated December 2019 | Ontruzant (trastuzumab-dttb)<br><br>Samsung Bioepis<br>Merck & Co | TBD Upon Launch | | | |
| March 2019 | Anticipated December 2019 | Trazimera (trastuzumab-qyyp)<br><br>Pfizer | TBD Upon Launch | | | |

## Biosimilar Pipeline *(continued)*

| Approval Date | Launch Date | Biosimilar Name | Biosimilar WAC / Year Cost | Reference Product | Reference Product WAC / Year Cost | Disease Category* |
|---|---|---|---|---|---|---|
| June 2019 | July 2019 | Kanjinti** (trastuzumab-anns)<br>Amgen<br>Allergan | $192,257.52 | Herceptin (trastuzumab) | $226,895.76 (dosing at 6mg/kg/wk) | **Cancer:** Treatment of Human Epidermal growth factor Receptor 2 (HER2) adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer |
| August 2017 | Anticipated 2023 | Cyltezo™ (adalimumab-adbm)<br>Boehringer Ingelheim | TBD Upon Launch | Humira (adalimumab) | $67,263 | **Immunosuppressant:** Treatment of ankylosing spondylitis, juvenile idiopathic arthritis, rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and/or ulcerative colitis |
| Expected FDA Review November 2019 | Anticipated 2023 | Abrilada (adalimumab, aka PF-06410293)<br>Pfizer | TBD Upon Launch | | | |
| July 2019 | Anticipated 2023 | Hadlima (adalimumab)<br>Biogen<br>Samsung Bioepis<br>Merck & Co | TBD Upon Launch | | | |
| September 2016 | Anticipated 2023 | Amjevita™ (adalimumab-atto)<br>Amgen | TBD Upon Launch | | | |
| October 2018 | Anticipated 2023 | Hyrimoz (adalimumab-adaz)<br>Sandoz | TBD Upon Launch | | | |
| June 2018 | July 2018 | Fulphila™** (pegfilgrastim-jmdb)<br>Mylan<br>Biocon | $4,175 | Neulasta (pegfilgrastim) | $6,231 | **Hematopoietic:** Reduce incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. |
| November 2018 | January 2019 | Udenyca ** (pegfilgrastim-cbqv)<br>Coherus | $4,175 | | | |

## Biosimilar Pipeline *(continued)*

| Approval Date | Launch Date | Biosimilar Name | Biosimilar WAC / Year Cost | Reference Product | Reference Product WAC / Year Cost | Disease Category* |
|---|---|---|---|---|---|---|
| 11/5/2019 | December 2019 | Ziextenzo ** (pegfilgrastim, aka LA-EP2006) Sandoz | $3925 | Neulasta (pegfilgrastim) | $6,231 | **Hematopoietic:** Reduce incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. |
| Expected FDA Review TBD | To Be Determined | Lapelga™ (pegfilgrastim, aka CHS-1701) Intas Apotex Accord | TBD Upon Launch | | | |
| Expected FDA Review TBD | To Be Determined | Grastofil (filgrastim) Intas Apotex Accord | TBD Upon Launch | Neupogen (filgrastim) | $5,314 | **Hematopoietic:** To reduce the incidence of infection in patents receiving chemotherapy, reduce the duration and time to recovery from neutropenia caused by chemotherapy, mobilization of progenitor blood cells for collection by leukapheresis, and reducing the incidence and duration of complications due to severe neutropenia. |
| Expected FDA Review TBD | To be determined | Filgrastim Kashiv (filgrastim) Kashiv AE Companies Amneal Adello Biologics | TBD upon Launch | | | |
| CRL 9/25/19 | Anticipated 4Q 2019 | TX01 (filgrastim) Tanvex | TBD Upon Launch | | | |
| March 2015 | September 2015 | Zarxio®** (filgrastim-sndz) Sandoz | $4,390 | | | |
| August 2012 | 2015 | Granix®** (tbo-filgrastim) Teva | $3,999 | | | |
| July 2018 | October 2018 | Nivestym™** (filgrastim-aafi) Hospira Pfizer | $3,504 | | | |

## Biosimilar Pipeline *(continued)*

| Approval Date | Launch Date | Biosimilar Name | Biosimilar WAC / Year Cost | Reference Product | Reference Product WAC / Year Cost | Disease Category* |
|---|---|---|---|---|---|---|
| December 2019 | Anticipated December 2019 | Avsola (infliximab-axxq aka ABP 710)<br><br>Amgen | TBD Upon Launch | Remicade (infliximab) | $49,340 | **Immunological Agent:** Ankylosing spondylitis, Crohn's disease (fistulizing), adult, Crohn's disease, adult and pediatric (6 years or older), Plaque psoriasis, Psoriatic arthritis, Rheumatoid arthritis in combination with methotrexate, Ulcerative colitis, adult |
| April 2017 | July 2017 | Renflexis®** (infliximab-abda)<br><br>Samsung Bioepis<br>Merck & Co | $31,831 | | | |
| April 2016 | November 2016 | Inflectra®** (infliximab-dyyb)<br><br>Celltrion<br>Pfizer | $39,980 | | | |
| November 2018 | Anticipated Q 3-4 2019 | Truxima™ (rituximab-abbs)<br><br>Celltrion<br>Teva | TBD Upon Launch | Rituxan (rituximab) | $40,712 | **Cancer:** Treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis. |
| July 2019 | Anticipated Q 3-4 2019 | Ruxience (rituximab-pvvr)<br><br>Pfizer | TBD Upon Launch | | | |

*Indications for the biosimilars may vary from the originator and from each other, and are continually evolving. Indications listed here are for the originator product.

**Indicate launched products.

*The above information was assembled from government and clinical resources for knowledge purposes only. Information and drugs were selected by clinicians based on therapy and potential clinical impact without any manufacture affiliations or conflicts of interest. Approval status, dates, and WAC price are subject to variation. This document should not be exclusively used for decision-making purposes. WAC pricing data should be used for benchmarking purposes only. Prices listed above should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer.*

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