

2020: FIRST HALF BIOSIMILAR PIPELINE REPORT



Be “in the know”. Confidio is committed to helping clients anticipate pharmaceutical trends and potential shifts in medication cost management. Confidio remains informed of the latest FDA drug approvals, medications in development, and upcoming specialty/biosimilar pipeline therapies.

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Look for these Biosimilar Pipeline Reports twice per year.

DID YOU KNOW?

Biosimilars are products designed to be similar in their effects or even interchangeable with biologic drugs. Biologic drugs are generally approved under a different statute, the Public Health Service Act (PHSA), than most other drugs, which are approved under the Food Drug and Cosmetic Act (FD&C Act). Examples of products approved through the PHS pathway are vaccines, immune globulins and anti-hemophilic products. Until recently, there was no way to promote competition for these products because there is no way to create generics for biologics. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), however, established a way to review and approve the next best thing to generics for biologics: biosimilars. Since 2009, many biosimilars have been reviewed and approved under this Act, successfully reducing prices by creating competition for their reference biologics.

In the past, a few drugs that are technically biological products were approved under the FD&C pathway. These products include insulins and growth hormones. Unfortunately, the FD&C Act has no pathway for approval of biosimilars for these products, preventing competition for them. The good news is that the BPCI Act contains a provision to allow transitioning of these products to being regulated as biologicals. This **transition occurred on March 23, 2020**, opening the door to creation of biosimilars for these important products.

Due in part to this transition, Confidio is “spinning off” the biosimilar section of its quarterly Pipeline Report. This report is the first edition of that spinoff; and we are pleased to note that the first biosimilar for a transitioned biologic (Semglee Basalog, reference product Lantus [insulin glargine]) has made its way into the report. We look forward to falling prices for insulin and other transitioned products in the months and years to come.

Recent Biosimilar Launches

- **Zirabev (bevacizumab-bvzr)** – Referenced to Avastin, 23% discount. Launched 1/6/2020.
- **Herzuma (trastuzumab-pkrb)** – Referenced to Herceptin, 11% discount. Launched 3/16/2020.
- **Ontruzant (trastuzumab-dttb)** – Referenced to Herceptin, 15% discount. Launched 4/15/2020.
- **Trazimera (trastuzumab-qyyp)** – Referenced to Herceptin, 22% discount. Launched 2/18/2020.
- **Ruxience (rituximab-pvvr)** – Referenced to Rituxan, 24% discount. Launched 1/23/2020.
- **Truxima (rituximab-abbs)** – Referenced to Rituxan, 10% discount. Launched 11/11/2019.

Orange boxes denote launched products

| Approval Date | Launch Date | Biosimilar Name | Biosimilar WAC/ Year Cost | Reference Product | Reference Product WAC/ Year Cost | Disease Category** |
|--------------------------------|-------------------------------|---|------------------------------|---------------------------------|-------------------------------------|--|
| 9/14/2017 | 7/18/2019 | Mvasi (bevacizumab-awwb) Amgen Allergan | \$123,286.80 | Avastin (bevacizumab) | \$144,872 | 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 |
| 6/27/2019 | 1/6/2020 | Zirabev (bevacizumab-bvzr) Pfizer | \$111,639 | | | |
| Estimated 12/27/2020 | Estimated 1Q2021 | Bmab-100 Apollo; MYL-14020 Biocon Mylan | TBD Upon Launch | | | |
| Estimated 9/2020 | Estimated 9/2020 | SB-8 Merck Samsung Bioepis | TBD Upon Launch | | | |
| 8/30/2016 | Estimated 2020-2029 | Erelzi® (etanercept-szsz) Sandoz | TBD Upon Launch | Enbrel (etanercept) | \$67,184 | Immunosuppressant: Ankylosing spondylitis, Juvenile idiopathic arthritis (2 years or older), Plaque psoriasis adult, Psoriatic arthritis, Rheumatoid arthritis |
| 4/25/2019 | Estimated 2020-2029 | Eticovo (etanercept-ykro) Samsung Bioepis | TBD Upon Launch | | | |

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|---------------|-------------|--|---------------------------|---|---|--|
| 5/15/2018 | 11/14/2018 | Retacrit™ (epoetin alfa-epbx) Hospira Pfizer Vifor Pharma | \$154 | Epogen Procrit (Epoetin Alfa) | Epogen - \$232 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. |
| 12/14/2018 | 03/16/2020 | Herzuma (trastuzumab-pkrb) Nippon Kayaku Celltrion Teva | \$204,204 | Herceptin (trastuzumab) | \$226,896 | Cancer: Treatment of human epidermal growth factor receptor 2 (HER2) adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer. |
| 6/13/2019 | 7/18/2019 | Kanjinti (trastuzumab-anns) Amgen Allergan | \$192,258 | | | |
| 12/1/2017 | 12/2/2019 | Ogivri (trastuzumab-dkst) Mylan Biocon | \$192,244 | | | |
| 1/18/2019 | 04/15/2020 | Ontruzant (trastuzumab-dttb) Samsung Bioepis Merck & Co | \$192,847 | | | |
| 3/11/2019 | 2/18/2020 | Trazimera (trastuzumab-qy-yp) Pfizer | \$176,249 | | | |

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| 11/15/2019 | Estimated 11/20/2023 | Abrilada (adalimumab, aka PF-06410293) Pfizer | 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. |
| 9/23/2016 | Estimated 1/31/2023 | Amjevita™ (adalimumab-atto) Amgen | TBD Upon Launch | | | |
| 8/25/2017 | Estimated 7/1/2023 | Cyltezo™ (adalimumab-adbm) Boehringer Ingelheim | TBD Upon Launch | | | |
| 7/23/2019 | Estimated 6/30/2023 | Hadlima (adalimumab) Biogen Samsung Bioepis Merck & Co | TBD Upon Launch | | | |
| 10/30/2018 | Estimated 9/30/2023 | Hyrimoz (adalimumab-adaz) Sandoz | TBD Upon Launch | | | |
| Estimated 6/2020 | Estimated 6/2020 | Semglee Basalog; MYL-1501D Biocon Mylan | TBD Upon Launch | | | |

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| 6/4/2020 | 7/2018 | Fulphila™ (pegfilgrastim-jmdb) Mylan 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. |
| 11/2/2018 | 1/3/2019 | Udenyca (pegfilgrastim-cbqv) Coherus | \$4,175 | | | |
| 11/4/2019 | 11/8/2019 | Ziextenzo (pegfilgrastim, aka LA-EP2006) Sandoz | \$3925 | | | |
| Estimated 6/2020 | Estimated 6/2020 | HSP-130; PF 06881894 Hospira; Pfizer; Biorasi | TBD Upon Launch | | | |
| Expected FDA Review TBD | To Be Determined | Lapelga™ (pegfilgrastim, aka CHS-1701) Intas Apotex Accord | TBD Upon Launch | | | |
| Estimated 10/24/2020 | Estimated 10/2020 | Rolontis HM10460A; HNK460; SPI-2012 Hanmi Pharmaceutical; Spectrum | TBD Upon Launch | | | |

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|-------------------------------|------------------------|---|---------------------------|--------------------------|----------------------------------|---|
| 8/29/2012 | 11/11/13 | Granix® (tbo-filgrastim) Teva | \$3,999 | 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. |
| 7/20/2018 | 9/2018 | Nivestym™ (filgrastim-aafi) Hospira Pfizer | \$3,504 | | | |
| 3/6/2015 | 9/3/2015 | Zarxio® (filgrastim-sndz) Sandoz | \$4,390 | | | |
| Expected FDA Review TBD | To Be Determined | Filgrastim Kashiv TPI G-CSF (filgrastim) Kashiv AE Companies Amneal Adello Biologics | TBD Upon Launch | | | |
| Expected FDA Review TBD | To Be Determined | Grastofil (filgrastim) Intas Apotex Accord | TBD Upon Launch | | | |
| CRL 9/25/19 | Anticipated 4Q 2019 | TX01 (filgrastim) Tanvex | TBD Upon Launch | | | |

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| 4/5/2016 | 11/28/2016 | Inflectra® (infliximab-dyyb) Celltrion Pfizer | \$19,872 | Remicade (infliximab) | \$24,524 | 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. |
| 4/21/2017 | 7/24/2017 | Renflexis® (infliximab-abda) Samsung Bioepis Merck & Co | \$15,821 | | | |
| 12/6/2019 | Estimated 2020 | Avsola (infliximab-axxq aka ABP 710) Amgen | TBD Upon Launch | | | |
| 12/13/2017 | To Be Determined | Ixifi PF-06428179 (infliximab-qbtx) Pfizer | TBD Upon Launch | | | |
| 7/23/2019 | 1/23/2020 | Ruxience (rituximab-pvvr) Pfizer | \$36,997 | Rituxan (rituximab) | \$48,478 | Cancer: Treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis. |
| 11/18/2018 | 11/11/2019 | Truxima™ (rituximab-abbs) Celltrion Teva | \$43,633 | | | |
| Estimated 4Q 2020 | Estimated 4Q 2020 | ABP 798 Amgen; Allergan | 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.

References

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 manufacturer 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.

1. DRUGDEX® System, 2020. <http://micromedexsolutions.com>. Greenwood Village, CO: Thomson Micromedex.
2. IPD Analytics, 2020. <https://ipdanalytics.com>. Bay Harbor Islands, FL.