

2020: DECEMBER BIOSIMILAR PIPELINE REPORT



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DID YOU KNOW?

Biosimilar products were initially slow to catch on, but the rate of uptake has increased over the last couple of years. The opposing forces of cost-saving measures such as formulary placement and restrictions, and provider and payer reluctance that dampen adoption, compete to drive the overall biosimilar adoption rate. Recently, cost-saving measures have been dominant over payer and provider reluctance in this equation. This is not surprising, given the economics in the industry: it has been estimated that annual savings in the US due to biosimilar use will be \$6.5 billion per year by the end of 2020--and that this figure will grow.

There are other factors that play into biosimilar adoption rate, albeit less impactful ones. For example, unlike generics of non-biologic drugs, currently available biosimilars are not interchangeable with their reference products (meaning that any switch from a reference product requires a new prescription). Also, for some products, biosimilar manufacturers are not pursuing FDA approval for all labeled indications of the reference products. Oncologists in particular seem to be overlooking these barriers: uptake of biosimilars with oncology indications is somewhat greater than that for other biosimilar products.

Recent Biosimilar Launches

- **Semglee (insulin glargine)** – Referenced to Lantus, 65% discount. Launched 8/31/2020.
- **Avsola (infliximab-axxq)** – Referenced to Remicade, 49% discount. Launched 5/26/2020.

New Biosimilars in Development

- **Hulio (pegfilgrastim)** – Referenced to Neulasta.
- **Myl-1601D (insulin aspart)** – Referenced to Novolog Flexpen.

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 4Q2020	Estimated 4Q2020	SB-8 Merck Samsung Bioepis	TBD Upon Launch			
8/30/2016	Estimated 2028-2029	Erelzi® (etanercept-szszs, aka GP2015) 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 2028-2029	Eticovo (etanercept-ykro, aka SB4) 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-qyyp) Pfizer	\$176,249			

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11/15/2019	Estimated 11/20/2023	Abrilada-afzb (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, aka ABP 501) Amgen	TBD Upon Launch			
8/25/2017	Estimated 7/1/2023	Cyltezo™ (adalimumab- adbm, aka BI 695501) Boehringer Ingelheim	TBD Upon Launch			
7/23/2019	Estimated 6/30/2023	Hadlima (adalimumab- bwvd, aka SB5) Biogen Samsung Bioepis Merck & Co	TBD Upon Launch			
7/6/2020	Estimated 7/31/23	Hulio (adalimumab-fkjp, aka FKB327) Fujifilm Kyowa Kirin; Mylan; Biocon	TBD Upon Launch			
10/30/2018	Estimated 9/30/2023	Hyrimoz (adalimumab-adaz, aka GP2017) Sandoz	TBD Upon Launch			

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6/11/2020	8/31/2020	Semglee (insulin glargine, aka MYL-1501D) Biocon Mylan	WAC per ml: \$9.87 (note this is not annual cos)	Lantus (insulin glargine)	WAC per ml: \$28.35 (note this is not annual cos)	Anti-diabetic
6/4/2018	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-bmez, aka LA-EP2006) Sandoz	\$3,925			
6/10/20	Estimated 2020	Nyvepria (pegfilgrastim-apgf, aka HSP-130; PF 06881894) Hospira; Pfizer; Biorasi	TBD Upon Launch			
Expected FDA Review TBD	To Be Determined	Lapelga Neupeg™ (pegfilgrastim, aka CHS-1701) Intas Apotex Accord	TBD Upon Launch			
Estimated 4Q2020	Estimated 4Q2020	Rolontis (eflapegrastim ["biobetter" of Neulasta], aka HM10460A; HNK460; SPI-2012) Hanmi Pharmaceutical; Spectrum	TBD Upon Launch			
Estimated 3/2021	Estimated 3/2021	MSB11455 Fresenius; Dr. Reddy's	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	Estimated 4Q 2019	TX01 (filgrastim) Tanvex	TBD Upon Launch			
Estimated 2Q2021	Estimated 2H2021	MYL-1601D Mylan; Biocon	TBD Upon Launch			

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4/5/2016	11/28/2016	Inflectra [®] (infliximab-dyyb) Celltrion Pfizer	\$21,528	Remicade (infliximab)	\$26,567	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.
4/21/2017	7/24/2017	Renflexis [®] (infliximab-abda) Samsung Bioepis Merck & Co	\$17,140			
12/6/2019	5/26/20	Avsola (infliximab-axxq aka ABP 710) Amgen	\$13,650			
12/13/2017	To Be Determined	Ixifi (infliximab-qbtx; aka PF-06438179) 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 4Q2020	Estimated 4Q2020	ABP 798 Amgen; Allergan; Abbvie	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

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1. Bernstein Research. Biosimilars (Sept update): A \$2.8B US business growing quickly; \$5.6B US savings; Amgen and Pfizer establish a lead. Published September 16, 2020
2. DRUGDEX[®] System, 2020. <http://micromedexsolutions.com>. Greenwood Village, CO: Thomson Micromedex.
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