

PIPELINE REPORT

Biosimilar Drugs

February 2019



PIPELINE DRUG	MANUFACTURER	CURRENT STATUS	ANTICIPATED APPROVAL	COMMENTS
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filgrastim adello biosimilar	Adello Biologic	Filing accepted for review by FDA	2018	Estimated Launch: TBD Innovator Brand: Neupogen (filgrastim)
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A human granulocyte colony-stimulating factor (G-CSF). Adello announced BLA accepted for review by the FDA September 11, 2017. Filed for the same indications as Neupogen

pegfilgrastim biosimilar Lapelga	Apotex Instas	351(k) Filed	2018	Estimated Launch: TBD Innovator Brand: Neulasta (pegfilgrastim)
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A pegfilgrastim biosimilar to Amgen's Neulasta. Apotex announced FDA had accepted BLA in December 2014 and that product will be marketed in the US through ApoBiologix. In a December 2016 press release, ApoBiologix stated the 'FDA is actively reviewing the application for Lapelga.'

filgrastim biosimilar Grastofil	Apotex Intas	351(k) Filed	2018	Estimated Launch: TBD (2019) Innovator Brand: Neupogen (filgrastim)
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A human granulocyte colony-stimulating factor (G-CSF) biosimilar to Amgen's Neupogen. It binds to specific receptors on granulocytes to stimulate proliferation, differentiation, and end-cell functional activation. Filed for the same indications as Neupogen.

trastuzumab-dttb Ontruzant SB3	Merck Samsung Bioepis	Approved	2019 (1/18/2019)	Estimated Launch: TBD (2019) Innovator Brand: Herceptin (trastuzumab)
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A HER2/neu receptor antagonist biosimilar to Merck's Herceptin for the adjuvant treatment of HER2-overexpressing breast cancer, metastatic breast cancer, and metastatic gastric cancer.

trastuzumab biosimilar Trazimera PF-05280014	Pfizer	BLA Filed	February 2019	Estimated Launch: TBD (2019) Innovator Brand: Herceptin (trastuzumab)
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A biosimilar to Herceptin, BLA rejected by the FDA April 2018 highlighting the need for additional technical information. In a third quarter 2018 results press release, Pfizer stated that the FDA has accepted its resubmitted biosimilar application and the 'goal date for a decision by the FDA is in the first-quarter 2019.'

bevacizumab biosimilar PF-06439535	Pfizer	351(k) Filed	July 2019	Estimated Launch: TBD (2019-2020) Innovator Brand: Avastin (bevacizumab)
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A monoclonal antibody (mAb) biosimilar to Avastin. Pfizer has completed a Phase III clinical trial and announced 3Q 2018 that the FDA had accepted its biosimilar application and 'goal date for a decision by the FDA is in second-quarter 2019.'

adalimumab biosimilar Imraldi SB5	Biogen Samsung Bioepis	BLA Filed	July 2019	Estimated Launch: June 20, 2023 Innovator Brand: Humira (adalimumab)
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An adalimumab biosimilar referencing Humira; FDA accepted BLA for Imraldi September 2018. This biosimilar is already approved in several countries outside of the U.S.A., including Europe and Canada.

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rituximab biosimilar PF-05280586	Pfizer	BLA Accepted	July 2019	Estimated Launch: TBD (2019) Innovator Brand: Rituxan (rituximab)
<p>A monoclonal antibody (mAb) in development as a potential biosimilar of Rituxan. In its 3Q 2018 results press release, Pfizer stated the FDA had accepted its biosimilar application and the 'goal date for a decision by the FDA is in third-quarter 2019.'</p>				
filgrastim biosimilar TX-01	Tanvex	BLA Filed	10/1/2019	Estimated Launch: TBD (2019) Innovator Brand: Neupogen (filgrastim)
<p>TX-01 is a proposed biosimilar to Amgen's Neupogen (filgrastim) a granulocyte colony-stimulating factor (G-CSF). Tanvex submitted its first BLA to the FDA October 2018</p>				
infliximab biosimilar ABP 710	Amgen	BLA Filed	10/17/2019	Estimated Launch: TBD (2019) Innovator Brand: Remicade (infliximab)
<p>ABP 710 is being investigated as a biosimilar candidate to infliximab, an anti-tumor necrosis factor alpha (anti-TNF) monoclonal antibody. Amgen submitted BLA December 17, 2018</p>				
etanercept-szsz Erelzi GP2015	Sandoz	Approved	8/30/2016	Estimated Launch: TBD (2019-2028) Innovator Brand: Enbrel (etanercept)
<p>Approved in August 2016 for all indications for which Enbrel approved. In July 2017, Sandoz filed to remove Erelzi's psoriatic arthritis and plaque psoriasis indications which the FDA agreed to January 2018. Currently in litigation for patent infringement with Amgen with trial set to begin June 2018.</p>				
adalimumab-atto Amjevita ABP-501	Amgen	Approved	9/23/2016	Estimated Launch: Settlement: 01/31/2023 Innovator Brand: Humira (adalimumab)
<p>Approved as a biosimilar to Humira in 2016. Settlement agreement between Amgen and AbbVie (manufacturer of Humira) to dismiss all pending litigation and launch of Amjevita in US 2023.</p>				
adalimumab-adbm Cyltezo BI 695501	Boehringer	Approved	8/25/2017	Estimated Launch: TBD (2020-2023) Innovator Brand: Humira (adalimumab)
<p>A tumor necrosis factor (TNF) blocker biosimilar to Humira with all of the same approved indications (except Hidradenitis Suppurativa) approved August 2017. Currently in litigation with AbbVie hoping to launch before 2023 target date.</p>				
bevacizumab-awwb Mvasi ABP 215	Amgen Allergan	Approved	9/14/2017	Estimated Launch: TBD (Mid-2019) Innovator Brand: Avastin (bevacizumab)
<p>A vascular endothelial growth factor-specific angiogenesis inhibitor indicated for the treatment of metastatic colorectal cancer (mCRC), non-squamous non-small cell lung cancer (NSCLC), glioblastoma, metastatic renal cell carcinoma (mRCC), and persistent, recurrent or metastatic carcinoma of the cervix</p>				

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trastuzumab-dkst Ogivri MYL-14010	Mylan Biocon	Approved	12/1/2017	Estimated Launch: TBD (Mid-2019) Innovator Brand: Herceptin (trastuzumab)
<p>A monoclonal antibody that interferes with the human epidermal growth factor receptor 2 (HER2)/neu receptor and approved for treatment of patients with breast or metastatic stomach cancer whose tumors overexpress the HER2 gene. The drug has not yet launched due to a licensing agreement Mylan signed with Roche, speculation the date will be in 2019-2020.</p>				
infliximab-qbtx Ixifi PF-06438179	Pfizer	Approved	12/13/2017	Estimated Launch: No US launch Plans Innovator Brand: Remicade (infliximab)
<p>A biosimilar to Remicade, Pfizer not planning to launch in the U.S.A. as they have Inflectra already released. Ixifi was developed prior to company's acquisition of Hospira (who developed Inflectra)</p>				
adalimumab-adaz Hyrimoz GP2017	Sandoz	Approved	10/31/2018	Estimated Launch: Settlement: 09/30/2023 Innovator Brand: Humira (adalimumab)
<p>A tumor necrosis factor (TNF) blocker biosimilar to Humira with all of the same approved indications (except Hidradenitis Suppurativa) approved August 2017. Sandoz announced October 2018 they had reached a licensing agreement with AbbVie that will permit Sandoz to launch its biosimilar version of Humira in the U.S.A. on September 30, 2023.</p>				
pegfilgrastim-cbqv Udenyca CHS-1701	Coherus Biosciences	Approved	11/2/2018	Estimated Launch: Available January 2019 Innovator Brand: Neulasta (pegfilgrastim)
<p>Biosimilar referencing Neulasta approved for same indications, approved November 2018 after first filing in 2017 resulted in CRL requesting additional information and reanalysis. Product available as of January 2019 however is currently pending an appeal by Amgen before the Federal Court to block production</p>				
rituximab-abbs Truxima CT-P10	Celltion Teva Pharmaceutical	Approved	11/28/2018	Estimated Launch: TBD (2018-2019) Innovator Brand: Rituxan (rituximab)
<p>The first monoclonal antibody (mAB) biosimilar to Rituxan to be approved for the treatment of adult patients with CD20-positive, B-cell non-Hodkins lymphoma (NHL). Teva and Celltion have reached a settlement agreement with Genentech, including entry term. The terms and conditions of that agreement are confidential at this time.</p>				
trastuzumab-pkrb Herzuma CT-P06	Celltion Teva Pharmaceutical	Approved	12/17/2018	Estimated Launch: TBD (2019) Innovator Brand: Herceptin (trastuzumab)
<p>A biosimilar referencing Herceptin for the treatment of HER2-positive breast cancer. This approval follows the CRL issued by the FDA in April 2018 noting observations related to company's manufacturing process. Celltion resubmitted BLA in June 2018. Note that Herzuma did not gain approval in the indication of HER2-positive gastric cancer.</p>				