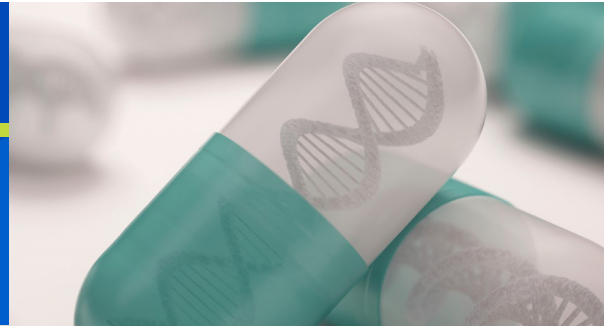


PIPELINE REPORT

Biosimilar Drugs

July 2018



PIPELINE DRUG	MANUFACTURER	CURRENT STATUS	ANTICIPATED APPROVAL	COMMENTS
epoetin alfa biosimilar Retacrit	Hospira Pfizer	351(k) Filed	2018 May 2018	Estimated Launch: TBD (2018) Innovator Brand: Epogen/Procrit (epoetin alfa) Annual Sales (\$ million): \$3,079
<p>Retacrit is a biosimilar to Amgen's Epogen and Janssen's Procrit. It is an erythropoiesis-stimulating agent (ESA) for the treatment of anemia. May 25, 2017 FDA Advisory Committee voted 14-1 in favor of approval for all Epogen indications; IV/SC</p>				
trastuzumab biosimilar ABP 9801	Amgen Allergan	351(k) Filed	2018 05/31/2018	Estimated Launch: TBD (2019?) Innovator Brand: Herceptin (trastuzumab) Annual Sales (\$ million): \$2,808
<p>Biosimilar to Herceptin for the treatment of patients with human epidermal growth factor receptor 2-positive (HER2-positive) early breast cancer; IV infusion</p>				
filgrastim biosimilar	Adello Biologic	351(k) Filed	2018 July 2018	Estimated Launch: TBD (2018) Innovator Brand: Neupogen (filgrastim) Annual Sales (\$ million): \$437
<p>A biosimilar to Amgen's Neupogen (filgrastim). It is a granulocyte colony-stimulating factor (G-CSF) to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever; SC</p>				
trastuzumab biosimilar Ontruzant SB3	Merck Samsung Bioepis	351(k) Filed	2018 08/19/2018	Estimated Launch: TBD (2019?) Innovator Brand: Herceptin (trastuzumab) Annual Sales (\$ million): \$2,808
<p>Humanized monoclonal antibody similar to Herceptin for the treatment of metastatic breast cancer in HER2-positive subjects, in combination with chemotherapy; IV</p>				
adalimumab biosimilar Humira Biosimilar GP2017	Sandoz	351(k) Filed	2018 09/16/2018	Estimated Launch: TBD (2019-2022) Innovator Brand: Humira (adalimumab) Annual Sales (\$ million): \$16,340

Biosimilar to Humira; anti-TNF-alpha monoclonal antibody for inflammatory conditions; SC

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PIPELINE DRUG	MANUFACTURER	CURRENT STATUS	ANTICIPATED APPROVAL	COMMENTS
pegfilgrastim biosimilar CHS-1701	Coherus	351(k) Filed	2018 11/03/2018	Estimated Launch: TBD (2018) Innovator Brand: Neulasta (pegfilgrastim) Annual Sales (\$ million): \$4,315
<p>Pegfilgrastim (Neulasta) biosimilar to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia; SC</p>				
pegfilgrastim biosimilar Lapelga	Apotex Intas	351(k) Filed	2018	Estimated Launch: TBD (2018) Innovator Brand: Neulasta (pegfilgrastim) Annual Sales (\$ million): \$4,315
<p>Pegfilgrastim (Neulasta) biosimilar to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia; SC</p>				
filgrastim biosimilar Grastofil	Apotex Intas	351(k) Filed	2018	Estimated Launch: TBD (pending approval) Innovator Brand: Neupogen (filgrastim) Annual Sales (\$ million): \$437
<p>Grastofil is a biosimilar to Amgen's Neupogen (filgrastim). It is a granulocyte colony-stimulating factor (G-CSF) to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever; SC</p>				