

PIPELINE REPORT

Biosimilar Drugs

July 2019



PIPELINE DRUG	MANUFACTURER	CURRENT STATUS	ANTICIPATED APPROVAL	COMMENTS
adalimumab biosimilar Imraldi SB5	Biogen Samsung Bioepis	351(k) Filed	5/31/2019	Estimated Launch: Settlement: 06/30/2023 Innovator Brand: Humira (adalimumab)
bevacizumab biosimilar PF-06439535	Pfizer	351(k) Filed	June 2019	Estimated Launch: TBD (2019-2020) Innovator Brand: Avastin (bevacizumab)
trastuzumab biosimilar Kanjinti ABP 980	Amgen Allergan	351(k) Filed	June 2019	Estimated Launch: TBD (2019-2020) Innovator Brand: Herceptin (trastuzumab)
rituximab biosimilar PF-05280586	Pfizer	351(k) Filed	July 2019	Estimated Launch: TBD (2019) Innovator Brand: Rituxan (rituximab)
filgrastim biosimilar TX-01	Tanvex	351(k) Filed	8/1/2019	Estimated Launch: TBD (2019) Innovator Brand: Neupogen (filgrastim)
pegfilgrastim biosimilar LA-EP2006	Sandoz	351(k) Filed	10/3/2019	Estimated Launch: TBD Innovator Brand: Neulasta (pegfilgrastim)
infliximab biosimilar ABP 710	Amgen	351(k) Filed	10/17/2019	Estimated Launch: TBD (2019) Innovator Brand: Remicade (infliximab)
adalimumab biosimilar PF-06410293	Pfizer	351(k) Filed	4Q 2019	Estimated Launch: Settlement: 11/20/2023 Innovator Brand: Humira (adalimumab)
filgrastim biosimilar	Adello Biologic	351(k) Filed	2019	Estimated Launch: TBD (FDA Approval) Innovator Brand: Neupogen (filgrastim)
pegfilgrastim biosimilar Lapelga INTP 5	Apotex Intas	351(k) Filed	2019	Estimated Launch: TBD (FDA Approval) Innovator Brand: Neulasta (pegfilgrastim)

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filgrastim biosimilar Grastofil	Apotex Intas	351(k) Filed	2019	Estimated Launch: TBD (FDA Approval) Innovator Brand: Neupogen (filgrastim)
etanercept-szszs Erelzi GP2015	Sandoz	Approved	8/30/2016	Estimated Launch: TBD (2019-2029) Innovator Brand: Enbrel (etanercept)
adalimumab-atto Amjevita ABP-501	Amgen	Approved	9/23/2016	Estimated Launch: Settlement: 01/31/2023 Innovator Brand: Humira (adalimumab)
adalimumab-adbm Cyltezo BI 695501	Boehringer	Approved	8/25/2017	Estimated Launch: Settlement: 07/01/2023 Innovator Brand: Humira (adalimumab)
bevacizumab-awwb Mvasi ABP 215	Amgen Allergan	Approved	9/14/2017	Estimated Launch: TBD (Mid 2019) Innovator Brand: Avastin (bevacizumab)
trastuzumab-dkst Ogivri MYL-14010	Mylan Biocon	Approved	12/1/2017	Estimated Launch: TBD (Mid 2019) Innovator Brand: Herceptin (trastuzumab)
infliximab-qbtX Ixifi PF-06438179	Pfizer	Approved	12/13/2017	Estimated Launch: No US launch plans Innovator Brand: Remicade (infliximab)
adalimumab-adaz Hyrimoz GP2017	Sandoz	Approved	10/31/2018	Estimated Launch: Settlement: 09/30/2023 Innovator Brand: Humira (adalimumab)
rituximab-abbs Truxima CT-P10	Celltion Teva Pharmaceutical	Approved	11/28/2018	Estimated Launch: TBD (2019) Innovator Brand: Rituxan (rituximab)
trastuzumab-pkrb Herzuma CT-P06	Celltion Teva Pharmaceutical	Approved	12/17/2018	Estimated Launch: TBD (2019) Innovator Brand: Herceptin (trastuzumab)