

Biosimilar Pipeline Report

July 2018

Pipeline Drug	Manufacturer	Current Status	Approval Date	Comments
1. filgrastim biosimilar	Adello Biologic	351(k) Filed	July 2018	Estimated Launch: TBD (2018) Innovator Brand: Neupogen (filgrastim)
2. trastuzumab biosimilar Ontruzant SB3	Merck Samsung Bioepis	351(k) Filed	08/19/2018	Estimated Launch: TBD (2019?) Innovator Brand: Herceptin (trastuzumab)
3. adalimumab biosimilar Humira Biosimilar GP2017	Sandoz	351(k) Filed	09/16/2018	Estimated Launch: TBD (2019-2022) Innovator Brand: Humira (adalimumab)
4. pegfilgrastim biosimilar CHS-1701	Coherus	351(k) Filed	11/03/2018	Estimated Launch: TBD (2018) Innovator Brand: Neulasta (pegfilgrastim)
5. rituximab biosimilar Truxima CT-P10	Celltrion Teva Pharmaceutical	351(k) Filed	11/29/2018	Estimated Launch: TBD (Dec. 2018+) Innovator Brand: Rituxan (rituximab)
6. pegfilgrastim biosimilar Lapelga	Apotex Intas	351(k) Filed	2018	Estimated Launch: TBD (2018) Innovator Brand: Neulasta (pegfilgrastim)
7. filgrastim Biosimilar Grastofil	Apotex Intas	351(k) Filed	2018	Estimated Launch: TBD (pending approval) Innovator Brand: Neupogen (filgrastim)
8. etanercept-szszs Erelzi GP2015	Sandoz		8/30/2016	Estimated Launch: TBD (2019 or 2028?) Innovator Brand: Enbrel (etanercept)
9. adalimumab-atto Amjevita ABP-501	Amgen		9/23/2016	Estimated Launch: Settlement: 01/31/2023 Innovator Brand: Humira (adalimumab)
10. adalimumab -adbm Cyltezo BI 695501	Boehringer		8/25/2017	Estimated Launch: Settlement: TBD (2020-2023) Innovator Brand: Humira (adalimumab)

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11. bevacizumab-awwb Mvasi ABP 215	Amgen Allergan		9/14/2017	Estimated Launch: TBD (Mid-2019) Innovator Brand: Avastin (bevacizumab)
12. trastuzumab- dkst Ogivri MYL-1401O	Mylan Biocon		12/1/2017	Estimated Launch: TBD (Mid 2019) Innovator Brand: Herceptin (trastuzumab)
13. infliximab-qbtx Ixifi PF-06438179	Pfizer		12/13/2017	Estimated Launch: no US launch plans Innovator Brand: Remicade (infliximab)
14. epoetin alfa- epbx Retacrit	Hospira Pfizer		5/15/2018	Estimated Launch: TBD (2018) Innovator Brand: Epogen / Procrit (epoetin alfa)
15. pegfilgrastim biosimilar Fulphila MYL-1401H	Mylan Biocon		6/4/2018	Estimated Launch: TBD (2018) Innovator Brand: Neulasta (pegfilgrastim)
16. filgrastim-sndz Zarxio EP2006; Zarzio	Sandoz		09/02/2015	Approval Date: 3/6/2015 Innovator Brand: Neupogen (filgrastim)
17. infliximab-dyyb Inflectra Remsima	Pfizer Celltrion		11/28/2016	Approval Date: 4/5/2016 Innovator Brand: Remicade (infliximab)
18. infliximab-abda Renflexis SB2	Merck Samsung Bioepis		07/24/2017	Approval Date: 4/21/2017 Innovator Brand: Remicade (infliximab)