

Biosimilarity: The FDA Perspective

Table 2.3 Potential U.S. Biosimilar Candidates through 2024

Brand	Generic Name	Therapeutic Category	Worldwide Annual Sales (2015) (\$millions)	Patent Expiry
Gonal-F	Follitropin alfa/beta	Genitourinary	767	Jun 2015
ReoPro	Abciximab	Blood	93	Jun 2015
Ovidrel	Choriogonadotropin alfa	Genitourinary	60	Jun 2015
Luveris	Lutropin alfa	Genitourinary	26	Jun 2015
Recothrom	Thrombin alfa	Blood	70	Jul 2015
Fabrazyme	Agalsidase beta	Various	602	Sep 2015
Neulasta	Pegfilgrastim	Oncology and immunomodulators	4,594	Oct 2015
Synagis	Palivizumab	Systemic antiinfectives	355	Oct 2015
Proleukin	Aldesleukin	Oncology and immunomodulators	124	Oct 2015
Thyrogen	Thyrotropin alfa	Oncology and immunomodulators	164	Nov 2015
Norditropin SimpleXx	Somatropin recombinant	Endocrine	1,112	Dec 2015
Helixate	Octocog alfa	Blood	396	Dec 2015
Puregon/Follistim	Follitropin beta	Genitourinary	335	Dec 2015
Provence	Sipuleucel-T	Oncology and immunomodulators	268	Dec 2015
PEGIntron	Peginterferon alfa-2b	Oncology and immunomodulators	198	Dec 2015
Lemtrada	Alemtuzumab	Central nervous system	156	Dec 2015
Orgalutran/Antagon	Ganirelix acetate	Genitourinary	59	Dec 2015
Lantus	Insulin glargine recombinant	Endocrine	7,267	Jun 2016
Bexxar	Tositumomab; iodine I 131 tositumomab	Oncology and immunomodulators	9	Sep 2016
Humira	Adalimumab	Musculoskeletal	14,085	Dec 2016
Macugen	Pegaptanib sodium	Sensory organs	5	Jan 2017
Somavert	Pegvisomant	Endocrine	220	Mar 2017
NovoMix 30	Insulin aspart recombinant, insulin aspart protamine recombinant	Endocrine	1,633	Jun 2017
Replagal	Agalsidase alfa	Various	481	Sep 2017
Increlex	Mecasermin (rDNA origin)	Endocrine	20	Sep 2017
Pediarix	DTP; hepatitis B and polio vaccine	Systemic antiinfectives	1,268	Dec 2017
Erbixut	Cetuximab	Oncology and immunomodulators	704	Feb 2018
Kepivance	Palifermin	Gastrointestinal	11	Aug 2018
Remicade	Infliximab	Musculoskeletal	5,852	Sep 2018

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