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U.S. Biosimilar Landscape

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About this report

Biosimilars are a promising product category, one that can provide patients and doctors with more affordable treatment options.

To date, there have been 48 approvals and 38 launches in the U.S. biosimilar market. As this market matures, its pipeline continues to grow. This reference guide is a useful tool to visualize and understand the current product landscape and potential future of this emerging market.

The market landscape chart is grouped by therapeutic class with Biosimilars and Follow-on Biologics organized in columns under the relevant molecule and Reference Product. Additional information regarding interchangeability designation ● and unbranded versions ▲ is highlighted via symbols.

The market pipeline charts show products that have not received FDA approval and are expected to launch in 1 to 4 years. These charts suggest a bright future for biosimilars, as they document a large number of existing and new suppliers investing in biosimilars.

The pipeline charts also capture the expansion of biosimilars into new therapeutic areas, including growth hormone, bone health, and immunomodulators.

U.S. biosimilar market landscape

As of March 11, 2024

Class	Supportive care			Oncology			Insulin		Ophthalmology
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Insulin Glargine	Insulin Lispro	Ranibizumab
Reference Products Manufacturer	NEUPOGEN Amgen	EPOGEN/ PROCRIT Amgen/J&J	NEULASTA Amgen	RITUXAN Genentech	AVASTIN Genentech	HERCEPTIN Genentech	LANTUS Sanofi ▲		LUCENTIS Genentech
Biosimilar Products Manufacturer Launch date or Approval date	ZARXIO Sandoz Sep 2015	RETACRIT Pfizer-Vifor Nov 2018	FULPHILA Mylan Jul 2018	TRUXIMA Teva Nov 2019	MVASI Amgen Jul 2019	KANJINTI Amgen Jul 2019	SEMGLEE Viatris-Mylan Nov 2021 ▲ ●		BYOOVIZ Biogen Jul 2022
	NIVESTYM Pfizer Oct 2018		UDENYCA Coherus Jan 2019	RUXIENCE Pfizer Jan 2020	ZIRABEV Pfizer Jan 2020	OGIVRI Mylan Nov 2019	REZVOGLAR Eli Lilly Apr 2023 ●		CIMERLI Coherus Oct 2022 ●
	RELEUKO Amneal Nov 2022		ZIEXTENZO Sandoz Nov 2019	RIABNI Amgen Jan 2021	ALYMSYS Amneal Oct 2022	TRAZIMERA Pfizer Feb 2020			
			NYVEPRIA Pfizer Dec 2020		VEGZELMA Celltrion Apr 2023	HERZUMA Teva March 2020			
			STIMUFEND Fresenius Feb 2023		AVZIVI Sandoz Dec 2023	ONTRUZANT Organon Apr 2020			
			FYLNETRA Amneal May 2023						
Follow-on biologics Manufacturer Launch date or Approval date							BASAGLAR Eli Lilly Dec 2016	ADMELOG Sanofi Dec 2017	

▲ Unbranded version is also available

● Interchangeability approval by the FDA. For more details on interchangeability, please visit https://www.fda.gov/media/151094/download

Approved but yet to launch

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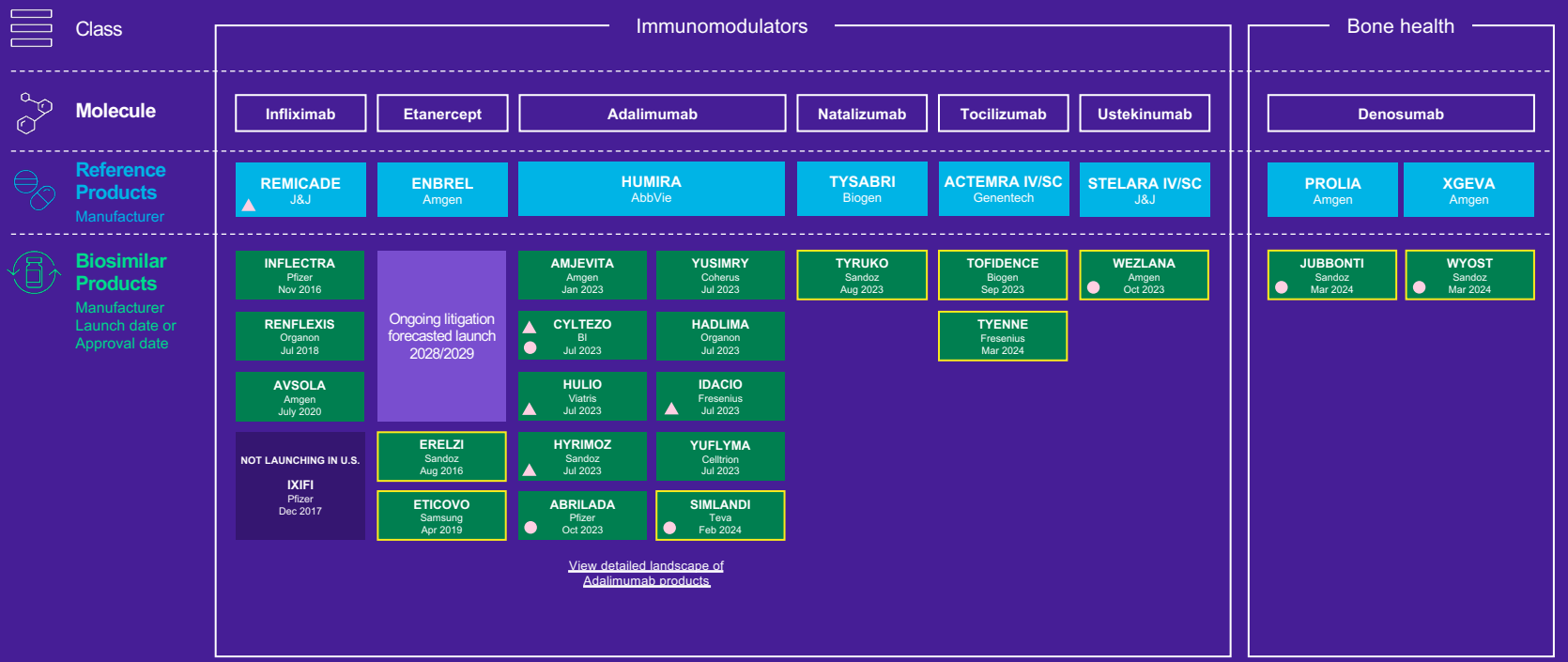

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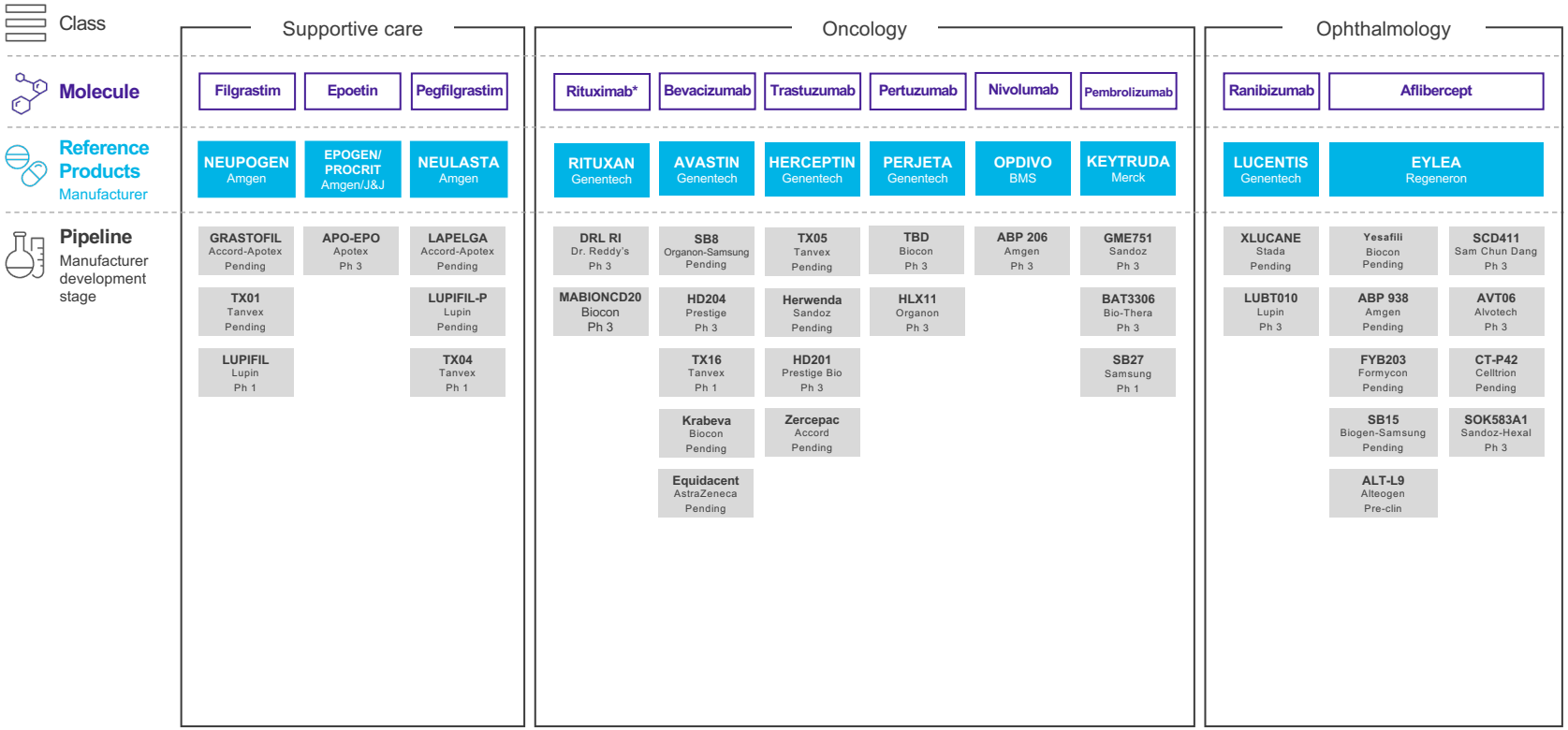
U.S. biosimilar pipeline landscape

As of March 11, 2024



Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.
*Rituximab products are also approved for indications outside of oncology such as autoimmune indications.

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U.S. biosimilar pipeline landscape

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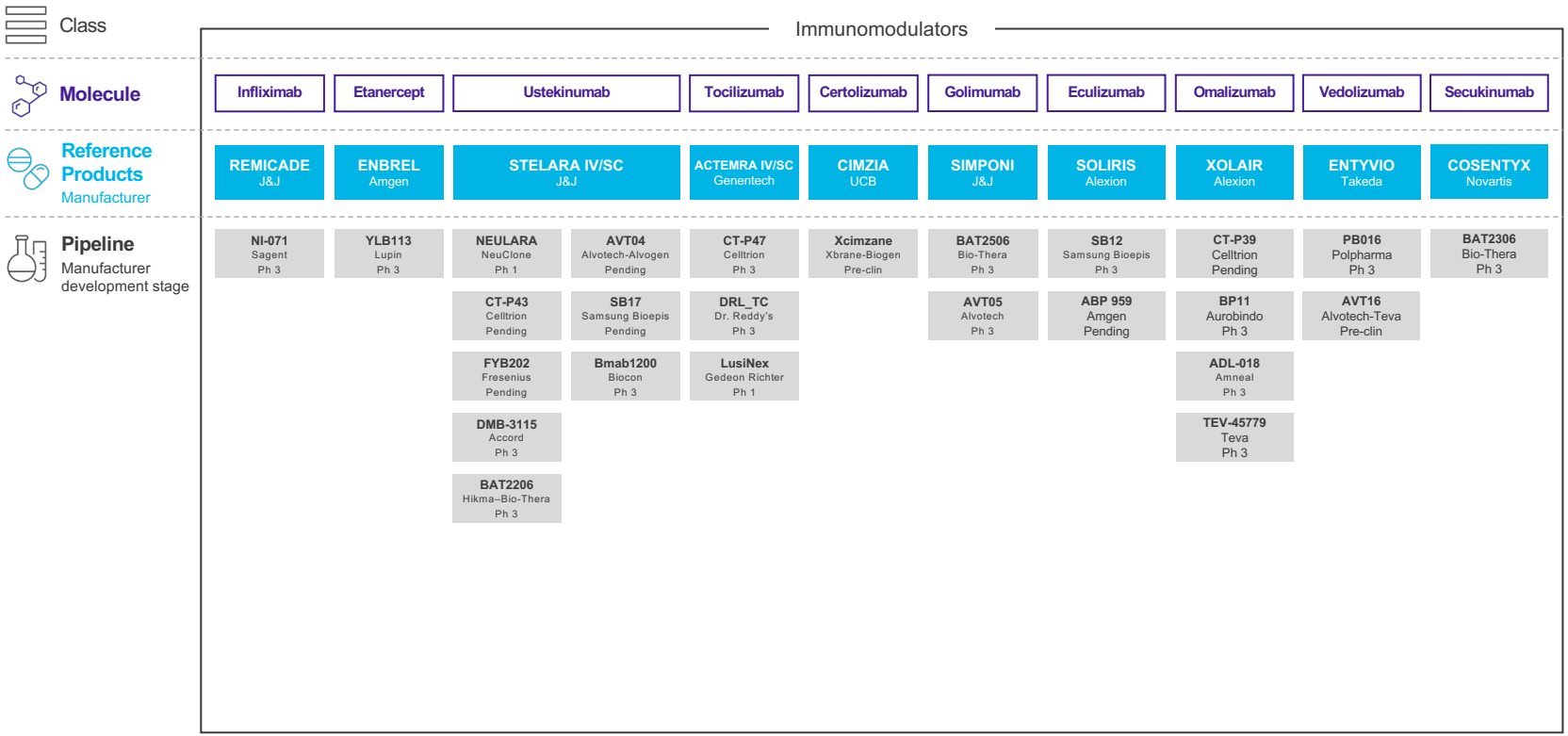

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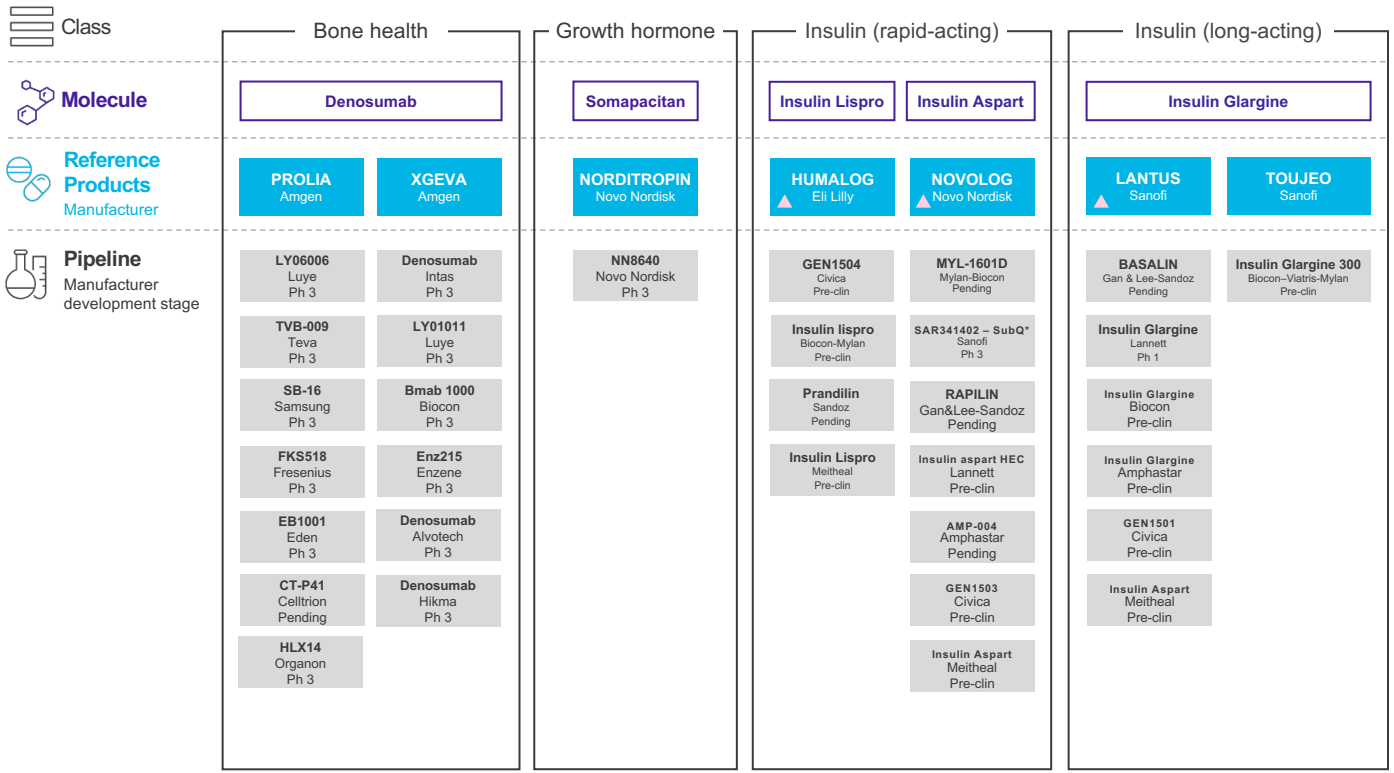

Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.
* Indicates that a biosimilar product has a different route of administration than its innovator product.

▲ Unbranded version is also available

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Definitions

Product	Definition
Reference products[1]	A reference product is a single biological product, already licensed (approved) by the FDA under section 351(a) of the Public Health Service Act, against which a proposed biosimilar or interchangeable product is compared. A reference product is approved based on, among other things, a full complement of safety and effectiveness data.
Biosimilars[1]	A biosimilar product is a biological product that is highly similar to and has no clinically meaningful differences in terms of safety or effectiveness from an existing FDA-licensed (approved) reference product.
Interchangeable biosimilars[1]	An interchangeable product is a biological product that meets the requirements for a biosimilar product and is approved based on information that is sufficient to show that it can be expected to produce the same clinical result as the reference product in any given patient; and for a biological product that is administered more than once to an individual, there is not a greater safety risk or risk of reduced efficacy from alternating or switching between use of the interchangeable product and its reference product. An interchangeable product can be substituted for the reference product without the intervention of the prescribing healthcare provider.
Unbranded reference products[1]	An unbranded reference product generally describes an approved brand name biological product that is marketed under its approved BLA without its brand name (proprietary name) on its label. An “unbranded reference product” is not an “interchangeable biosimilar.” However, an unbranded reference product is considered by the FDA to be equivalent to its brand name biological product because it is the same product as the brand name biological product under the same BLA.
Follow-on biologics	A follow-on biologic is a competing brand product to a reference product and was formerly approved under an NDA and subsequently deemed a BLA by the FDA.

Key: BLA – Biologics License Application; FDA – Food and Drug Administration; NDA – New Drug Application.

1. FDA. Purple Book. Last updated October 24, 2023. Accessed November 3, 2023. https://purplebooksearch.fda.gov/

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Find out how Cencora is creating sustainability and longevity for biosimilars.

For more information, please contact us here.

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