IPD ANALYTICS

INDUSTRY-LEADING DRUG LIFE-CYCLE INSIGHTS

Biosimilar Pipeline Report: Winter 2022/2023

What's Inside…

In this report, IPD Analytics provides an outlook for potential approvals and launches across the biosimilar landscape over the 2023–2026 horizon.

Our team of pharmacists, PhD scientists, and intellectual property attorneys continuously monitor and update our comprehensive pipeline intelligence database.

Our subscribers use this report as a companion to our online Clinical Development Tracker, which provides up-to-date clinical pipeline information on thousands of products across various disease classes and therapeutic areas. In tandem, these reports deliver insight into trending classes that will affect the competitive landscape and your drug spend.

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Also featured in the original report:

Tumor Necrosis Factor (TNF) Inhibitors

Humira (AbbVie) 40 mg/0.8 mL – Original Formulation

Humira (AbbVie) 40 mg/0.4 mL – High-Concentration Formulation

Enbrel (Amgen, Pfizer)

Remicade (Janssen)

Interleukin 6 Receptor (IL-6R) Antagonists

Actemra IV (Roche)

Actemra SC (Roche)

Insulin/Insulin Analogs

NovoLog (insulin aspart)/Novo Nordisk

Lantus (insulin glargine)/Sanofi

RANKL Inhibitors

Prolia/Xgeva (Amgen)

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Vascular Endothelial Growth Factor (VEGF) Inhibitors

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Colony-Stimulating Agents

Neulasta and Neulasta Onpro (Amgen)

Neupogen (Amgen)

Executive Summary

After slow initial adoption in the United States, biosimilars are now being included in medication lists and formularies. There is increased utilization of biosimilars, which are now being viewed by payers and providers as an opportunity for cost savings. The growing pipeline of near-term approvals and launches will further drive use and savings. Less expensive biosimilars are expected to play a critical role in controlling drug spend, as biologics continue to be a leading driver of increasing healthcare costs.

As expected, as utilization of biosimilars has increased, we note a trend of decreasing average sales prices (ASPs) of both reference products and those biosimilar products that have ASPs. Certain reference products have experienced dramatic decreases in sales, including Herceptin (25%), Neulasta Onpro (66%), and Remicade (60%).

On the heels of this uptick in overall biosimilar utilization, in 2023, we expect what is arguably the most significant loss-of-exclusivity event in the history of pharmaceuticals, when exclusivity expires for AbbVie's $20B drug, Humira. By mid-2023, we expect launches of six to eight biosimilars referencing the original formulation of Humira and three or four biosimilars referencing the new formulation. Availability of new-formulation biosimilar Humira may promote broader adoption of biosimilars by lowering one of the hurdles payers were expected to face in converting patients between old and new formulations.

The increase in utilization of biosimilars has also led to an increase in use of prior authorization, step therapy requirements, formulary tiering, tailored patient cost shares, and switching, in order to promote their use. A recent survey of insurers revealed the primary reason for preferring biosimilars is cost.

As these data evolve quickly, please refer to our pipeline coverage sections within our therapeutic class summaries on the Payer and Provider Insights portal, where you can find the latest information.

In addition, customized Clinical Pipeline Reports can be generated by applying user-specified filters to our online Clinical Development Tracker, a comprehensive database that includes current pipeline agents across more than 120 disease classes.

If you have any questions or feedback, contact us directly by emailing healthcare@ipdanalytics.com.

Figure 1. U.S. Biosimilar Competition: Volume of Share by Reference Market

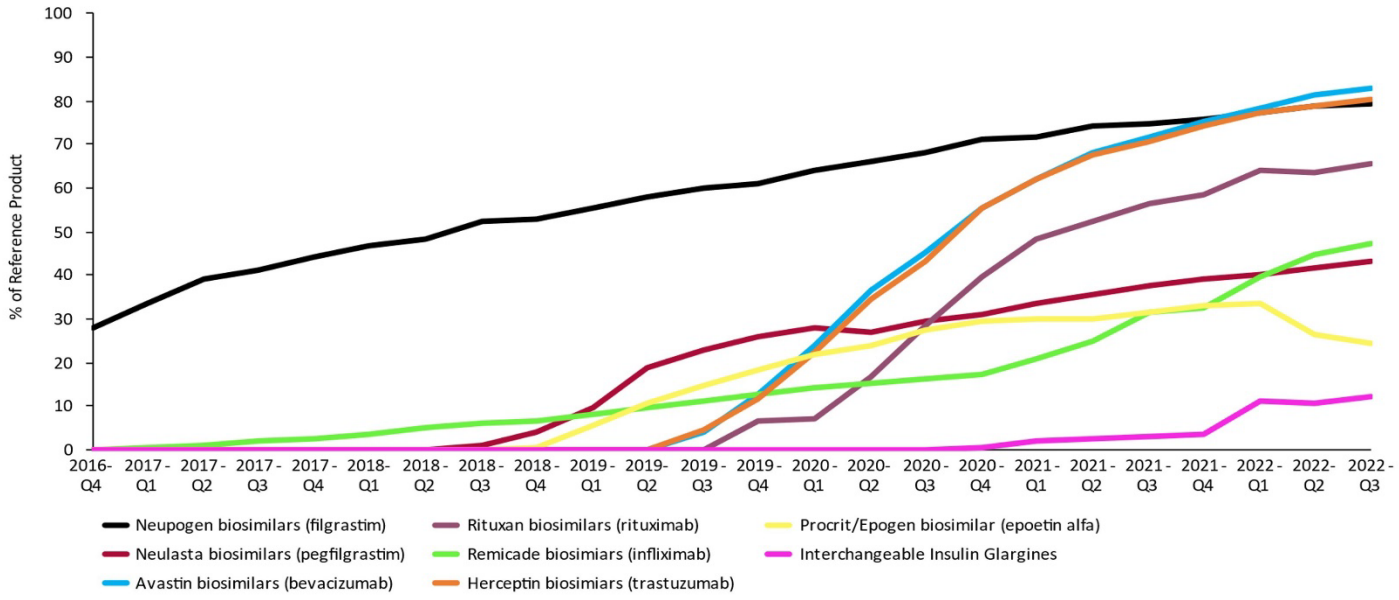

Table 1. ASP Trends for Reference and Biosimilar Products

Reference Product	Chemical Name	Date of First Biosimilar	Brand ASP at Biosimilar Launch (per Unit)	Brand ASP on 10/01/2022 (per Unit)	Brand ASP % Decrease	Current Number of Biosimilars Launched
Herceptin	trastuzumab	7/1/2019	$106.98	$79.62	25%	5
Avastin	bevacizumab	1/1/2019	$81.18	$65.78	20%	3
Rituxan	rituximab	7/1/2019	$94.97	$77.60	18%	3
Neulasta	pegfilgrastim	10/1/2018	$4422.37	$1487.76	66%	4
Neupogen	filgrastim	7/1/2015	$1.00	$0.93	7%	3
Epogen/Procrit	epoetin alfa	7/1/2018	$11.46	$7.90	31%	1
Remicade	infliximab	4/1/2018	$83.29	$33.04	60%	3

Table 2. ASP Trends for Biosimilar Products

Biosimilar Name	Chemical Name	Date of First ASP	First ASP (per Unit)	ASP on 01/01/2022 (per Unit)	ASP % Decrease	Current Number of Biosimilars Launched
Retacrit	epoetin alfa	7/1/2019	$10.11	$7.50	26%	1
Zirabev	bevacizumab	10/1/2020	$57.93	$33.40	42%	3
Truxima	rituximab	7/1/2020	$63.90	$46.81	27%	3
Fulphila	pegfilgrastim	10/1/2019	$311.18	$133.68	57%	4
Nivestym	filgrastim	7/1/2019	$0.63	$0.33	48%	3
Herzuma	trastuzumab	10/1/2020	$85.88	$46.60	46%	5
Ruxience	rituximab	10/1/2020	$65.66	$33.53	49%	3

In this report, we provide an outlook for potential approvals and launches across the biosimilar landscape over the 2023–2026 horizon (see Table 3). At the time of publication, the FDA has approved seven biosimilars in 2022.

Table 3. 2022 Biosimilar Approvals

Biosimilar Name	Manufacturer	Reference Product	Approval Month
Releuko	Adello/Amneal	Neupogen	February
Alymsys	Amneal	Avastin	April
Fylnetra	Adello/Amneal	Neulasta	May
Hadlima HC	Samsung Bioepis/Organon	Humira	August
Cimerli	Coherus	Lucentis	August
Stimufend	Fresenius/Dr Reddy's	Neulasta	September
Vegzelma	Celltrion	Avastin	September
Rezvoglar	Lilly	Lantus	November*

*Originally approved in December 2021, and not launched, but received interchangeable approval in November 2022

Table 4. Summary of Potential Biosimilars Included in Report

Drug	Reference Drug	Potential Timing of		Number of Potential Biosimilars Approvals or Launches	Approximate Annual Brand Sales
		Approval	Launch		
Adalimumab 40 mg/0.8 mL	Humira 40 mg/0.8 mL	Occurred	2023	8	>$5B
Adalimumab 40 mg/0.4 mL	Humira 40 mg/0.4 mL	Occurred	2023	5	>$20B
Etanercept	Enbrel	Occurred	2029	3	$9B
Infliximab	Remicade	2023–2024	2023–2024	1	$8B
Golimumab	Simponi/Simponi Aria	2023–2024	2024	1	$4B
Certolizumab	Cimzia	2024+	2024+	1	$2.8B
Tocilizumab IV	Actemra IV	2023–2025	2023–2025+	3	$2B
Tocilizumab SC	Actemra SC	2023–2025	2026–2027	3	$400M
Ustekinumab	Stelara	2023–2024	2023–2025	8	$14B
Omalizumab	Xolair	2024	2024–2025	2	$3B
Insulin aspart	NovoLog	2022–2024	2023–2024	3	$7B
Insulin glargine	Lantus	2023–2024	2023–2024	2	$11B
Denosumab	Prolia/Xgeva	2024–2026	2025–2026	9	$2.8B
Eculizumab	Soliris	2023	2023–2025	2	$2.6B
Natalizumab	Tysabri	2023	2023–2024	1	$2B
Trastuzumab	Herceptin	2022–2024+	2023–2024+	3	$1B
Rituximab	Rituxan	–	–	2	$2.8B
Bevacizumab	Avastin	2022+	2022–2023+	5	$1.3B
Aflibercept	Eylea	2023–2024	2024–2025 or 2032	7	$5.5B

Table 4. Summary of Potential Biosimilars Included in Report					
Drug	Reference Drug	Potential Timing of		Number of Potential Biosimilars Approvals or Launches	Approximate Annual Brand Sales
		Approval	Launch		
Ranibizumab	Lucentis	2023+	2024+	2	$2.3B
Pegfilgrastim	Neulasta	Occurred/–	2023+	4	$1B
Pegfilgrastim on-body injector	Neulasta Onpro	2022–2023+	2022–2023+	5	$4B
Filgrastim	Neupogen	2023–2024+	2023–2024+	3	$200M

Tumor Necrosis Factor (TNF) Inhibitors

Simponi/Simponi Aria (Janssen)

Biosimilar Drug	Studied Indication(s)	Route of Administration	Mechanism of Action
Golimumab	Psoriatic arthritis + extrapolation	Subcutaneous/ Intravenous	Anti-TNFα
Manufacturer (Drug)	**Phase**	**Potential Approval Date**	**Potential Launch Date**
Bio-Thera (BAT2506)	Phase 3	2023–2024	2024

Cimzia (UCB)

Biosimilar Drug	Studied Indication(s)	Route of Administration	Mechanism of Action
Certolizumab	Rheumatoid arthritis + extrapolation	Subcutaneous	Anti-TNFα
Manufacturer (Drug)	**Phase**	**Potential Approval Date**	**Potential Launch Date**
Xbrane/Biogen (Xcimzane)	Preclinical	2024+	2024+

Interleukin 12 and 23 Antagonists

Stelara* (Janssen)

Biosimilar Drug	Studied Indication(s)	Route of Administration	Mechanism of Action
Ustekinumab	Plaque psoriasis + extrapolation	Subcutaneous	IL-23 antagonist

Manufacturer (Drug)	Phase	Potential Approval Date	Potential Launch Date
Alvotech, Teva (AVT04)	Pending approval	2023	2H 2023
Amgen (ABP 654)^	Pending approval	2023	2H 2023
Celltrion (CT-P43)	Phase 3	2023	2023–2024
Samsung Bioepis (SB17)	Phase 3	2023	2023–2024
Biocon (Bmab 1200)	Phase 3	2023–2024	2024
Formycon (FYB202)	Phase 3	2024	4Q 2024
Dong-A, Meiji Seika (DMB-3115)	Phase 3	2024	2024–2025
Bio-Thera, Hikma (BAT2206)	Phase 3	2024	2025

*Based on the routes of administration being evaluated in clinical trials, we expect biosimilar Stelara competitors to minimally seek FDA approval for subcutaneous (SC) biosimilar products. Assuming successful completion of Phase 3 SC biosimilar trials, it is possible that competitors may gain approval for intravenous (IV) Stelara biosimilars without conducting additional Phase 3 studies if they can provide sufficient human pharmacokinetic and immunogenicity data comparing IV and SC formulations.
^Seeking interchangeability.

Anti-IgE Antibody

Xolair (Novartis)

Biosimilar Drug	Studied Indication(s)	Route of Administration	Mechanism of Action
Omalizumab	Chronic idiopathic urticaria + extrapolation	Subcutaneous	Anti-IgE antibody
Manufacturer (Drug)	**Phase**	**Potential Approval Date**	**Potential Launch Date**
Teva (TEV-45779)	Phase 3	2024	2025
Celltrion (CT-P39)	Phase 3	2024	2024–2025

Complement Inhibitor

Soliris (Alexion)

Biosimilar Drug	Studied Indication(s)	Route of Administration	Mechanism of Action
Eculizumab	Paroxysmal nocturnal hemoglobinuria (PNH)	Intravenous	Complement inhibitor
Manufacturer (Drug)	**Phase**	**Potential Approval Date**	**Potential Launch Date**
Amgen (ABP 959)	Phase 3	2023	2024–2025
Samsung Bioepis (SB12)	Phase 3	2023	2023–2025

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Vascular Endothelial Growth Factor (VEGF) Inhibitors (cont.)

Eylea (Regeneron)

Biosimilar Drug	Studied Indication(s)	Route of Administration	Mechanism of Action
Aflibercept	Wet age-related macular degeneration	Intravitreal	Vascular endothelial growth factor inhibitor
Manufacturer (Drug)	**Phase**	**Potential Approval Date**	**Potential Launch Date**
Biogen, Samsung Bioepis (SB15)	Phase 3	2023	2024 or 2032
Sam Chun Dang (SCD411)	Phase 3	2023	2024 or 2032
Hexal, Sandoz (SOK583A1)	Phase 3	2024	2025 or 2032
Amgen (ABP 938)	Phase 3	2023	2024 or 2032
Celltrion (CT-P42)	Phase 3	2023	2024 or 2032
Momenta, Mylan, Viatris (M710, MYL-1701P)	Pending approval	2023	2024 or 2032
Alvotech, Alvogen, Teva (AVT06)	Phase 3	2023–2024	2024 or 2032

About Payer & Provider Insights

IPD's Payer & Provider Insights combine advanced pharmaceutical landscape market visibility with a team of Executive Clinical Pharmacists to provide comprehensive pharmacy and therapeutic management strategy, supporting formulary, clinical, contracting, and market-access decisions.

Understand Key Clinical, Cost, Utilization, Reimbursement, and Market-Competition Factors

Review Formulary Management Considerations and Opportunities and Strategies and P&T Committee Planning Support

Anticipate Market Shifts, Pipeline Events, Manufacturer Life-Cycle Management Strategies, and Financial Implications

Access Published Guidelines, Health Outcomes, Pharmacoeconomics, and Clinical Trials