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Biosimilars: Updated Market Landscape

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Objectives

- Describe new guidance on biosimilars and biosimilar interchangeability
- Review biosimilars currently available on the market
- Highlight upcoming biosimilars in the specialty pipeline

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Overview of Biosimilars

Impact[1-2]

$36 billion

Savings since biosimilar entry to market in **2015**

$12.4 billion

Savings from biosimilars in **2023**

$180 billion

Projected savings from biosimilars for **2023-2027**

Impact

Biologics comprise **46%** of total medicine spending

$ bil

80 ion

Savings sin entry to m

avings from biosimilars for **2023-2027**

Definitions[3-4]

- **Biological products (biologics):** large, complex molecules produced through recombinant DNA technology in a living system; used to diagnose, prevent, treat, and cure diseases and medical conditions

- **Reference product:** an FDA approved biologic product against which a proposed biosimilar product is compared

- **Biosimilar:** product that is **highly similar** to and has **no clinically meaningful differences** from an existing FDA approved reference product

- **Interchangeable:** a biosimilar product fulfilling additional requirements that demonstrate its ability to produce the same clinical response as the reference product in any given patient; **it may be substituted** for a reference product without the intervention of the prescribing healthcare provider, depending on state pharmacy laws

Approval Pathway[5-6]

Reference Product: 351(a) Pathway

- Clinical Safety and Efficacy Study (for each indication)
- Clinical Pharmacology
- Product Quality
- Animal/Nonclinical

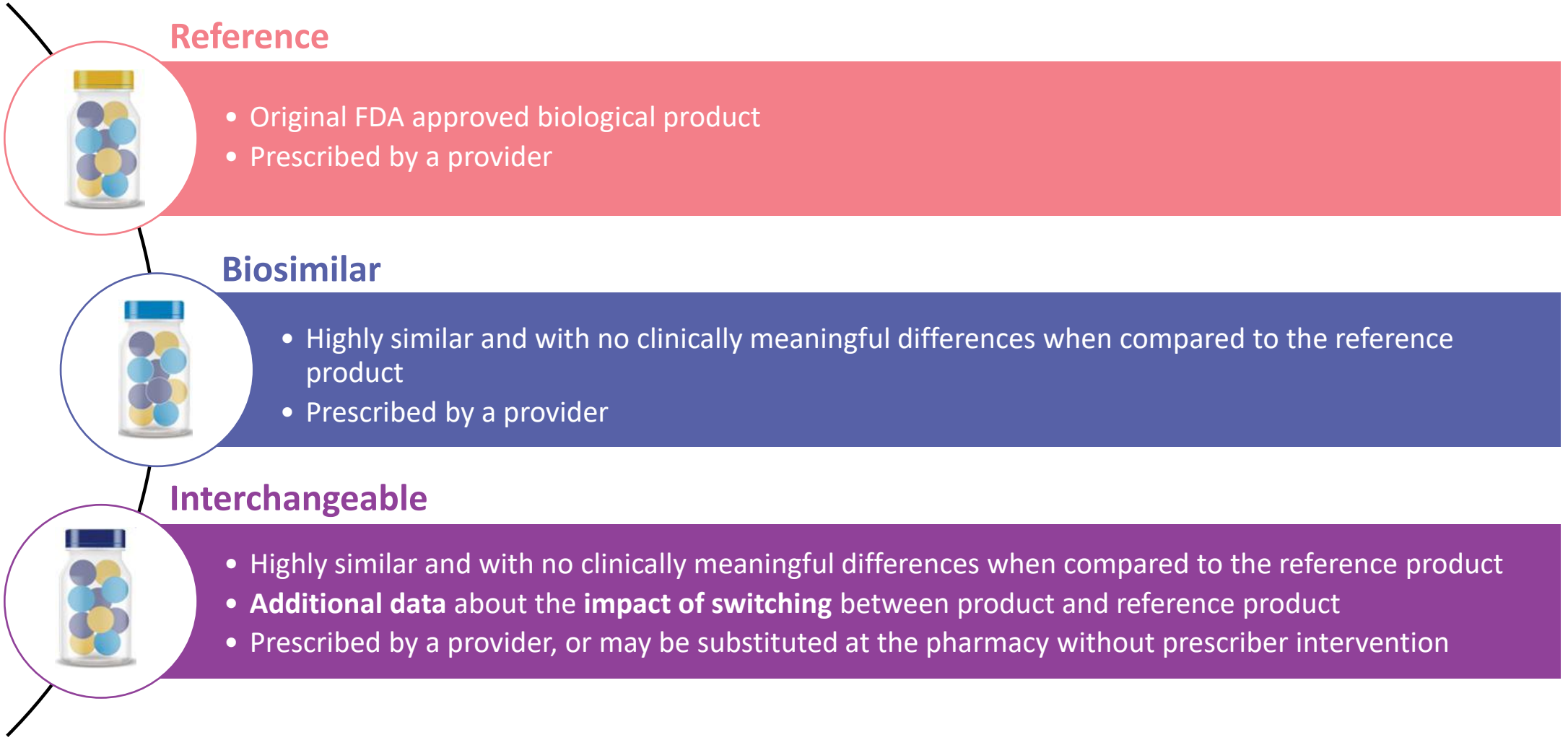
Biosimilar Product: 351(k) Pathway

- Additional Clinical Studies
- Clinical Pharmacology
- Product Quality
- Comparative Analytical Assessment

→ Physiochemical (structural) assays

Biological (functional) assays

Interchangeable Biosimilars



Reference

- Original FDA approved biological product
- Prescribed by a provider

Biosimilar

- Highly similar and with no clinically meaningful differences when compared to the reference product
- Prescribed by a provider

Interchangeable

- Highly similar and with no clinically meaningful differences when compared to the reference product
- **Additional data** about the **impact of switching** between product and reference product
- Prescribed by a provider, or may be substituted at the pharmacy without prescriber intervention

Interchangeable Biosimilars[7]

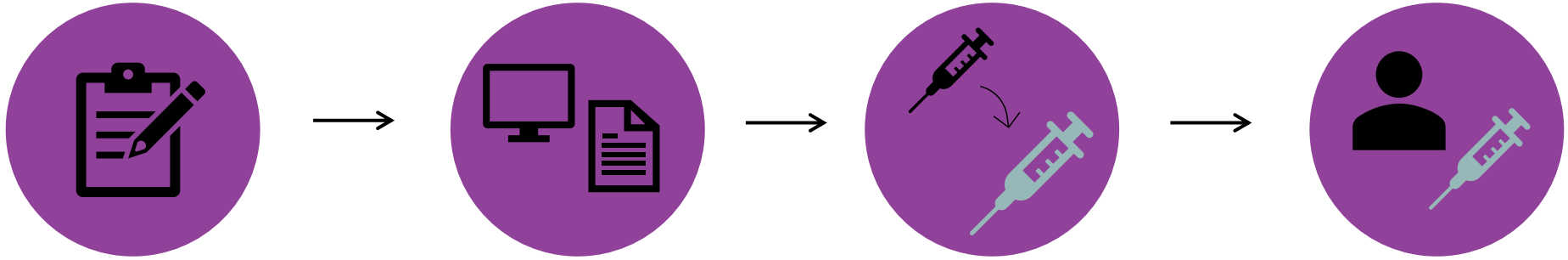
To be granted interchangeable status:

- Must meet the requirements for biosimilarity
- Must show that the biological product can be expected to produce the same clinical result as the reference product in any given patient
- **Switching Standard**: Must show the risk of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such switch

FDA-approved interchangeable biosimilars can be expected to produce the **same clinical result** as the reference product in any given patient, and the risk (safety and efficacy) of **switching between interchangeable biosimilar** and reference product is not greater than the risk of using the reference product without switching

Prescribing Biosimilars

- **Prescribing:**
  - Health care providers do not need to wait for a biosimilar to be approved as an interchangeable product to prescribe it; **companies must specifically seek an interchangeability determination**
- **Dispensing:**
  - Interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state laws
  - Substitution of non-interchangeable biosimilars requires approval from the prescriber



Doctor prescribes the reference product

Script goes to the pharmacy

Pharmacist substitutes interchangeable biosimilar for reference product

Patient receives interchangeable biosimilar

Updated Guidance

Medicare[8-9]

- All non-interchangeable biosimilars may be substituted as formulary maintenance changes:
  - Part D sponsors may treat formulary substitutions of all non-interchangeable biosimilars for their reference products as "maintenance changes" that **would not require explicit prior approval** by Centers for Medicare & Medicaid Services (CMS)
  - This option has previously been available only for interchangeable biological products
  - This means that midyear formulary substitutions would apply to all enrollees
- Part D sponsors meeting certain requirements as defined in the 2025 Final Rule and existing CMS regulations have the additional option to **immediately substitute** a new interchangeable biological product for a reference product and **provide notice** of the change to affected enrollees after making such change
  - Enrollees must be notified of maintenance changes at least 30 days prior to effective date of change

Maintenance changes are submitted to CMS and deemed approved 30 days after submission unless otherwise notified by CMS

Food and Drug Administration[10]

- **DRAFT Guidance:** The Food and Drug Administration (FDA) is **removing** its prior recommendation that a biosimilar drug applicant must submit **clinical switching studies** to demonstrate that a biosimilar is interchangeable with the biologic reference drug
- Instead, a biosimilar drug applicant may **submit a statement** to the FDA explaining why the existing data in a biologic license application would support the FDA's designation of the drug as interchangeable
    - Once designated as "interchangeable," pharmacists can substitute that product for a biologic without prescriber intervention
- Both biosimilars and interchangeable biosimilars can be used in the place of a reference product and are considered as safe and effective as the reference product
    - Accumulated experience regarding biosimilars has shown that biosimilars and interchangeable biosimilars have the **same safety and effectiveness**

Food and Drug Administration

Previous Guidance	Draft Guidance
Must meet the requirements for biosimilarity **AND** Submit clinical switching studies	Must meet the requirements for biosimilarity **AND** Submit a statement explaining why the existing data in a biologic license application would support the FDA's designation of the drug as interchangeable

FDA: Rationale

- Since publication of the Interchangeability Guidance, **the Agency has gained further experience** in evaluating the potential differences between proposed biosimilar products and their reference products
  - Analytical differences
  - Impact on clinical performance
- Currently available analytical technologies can **structurally characterize** highly purified therapeutic proteins and model in vivo functional effects
  - High degree of specificity and sensitivity using in vitro biological and biochemical assays

Legislation[11]

- S.2305, **Biosimilar Red Tape Elimination Act**
  - Introduced in Senate 7/13/2023, still in the **first stage** of the legislative process
- This bill removes certain requirements for biosimilars to be designated as interchangeable:
  - Establishes a presumption that an approved biosimilar is interchangeable with the reference product without the need for additional evidence from the manufacturer
  - Removes the applicable exclusivity periods for a first interchangeable biosimilar (i.e., a product that is the first interchangeable biosimilar to be approved with respect to the reference product).
- The FDA **may require** a manufacturer of a biosimilar to conduct a safety study with respect to switching or alternating between the biosimilar and the reference product, but only after the FDA briefs certain members of specified congressional committees to explain why the study is necessary

Current Biosimilars

Current Landscape[4]

Autoimmune:

- Actemra (tocilizumab)
- Enbrel (etanercept)
- Humira (adalimumab)
- Lantus (insulin glargine)
- Remicade (infliximab)
- Soliris (eculizumab)
- Stelara (ustekinumab)
- Tysabri (natalizumab)

Osteoporosis:

- Prolia and Xgeva (denosumab)

Oncology:

- Avastin (bevacizumab)
- Herceptin (trastuzumab)
- Rituxan (rituximab)

Ophthalmology:

- Eylea (aflibercept)
- Lucentis (ranibizumab)

Supportive Care:

- Epogen, Procrit (epoetin-alfa)
- Neulasta (pegfilgrastim)
- Neupogen (filgrastim)

Autoimmune

Reference Product	Biosimilar Name	Approval Date	Launch Date
Actemra (tocilizumab)	Tofidence (tocilizumab-bavi)	September 2023	May 2024
	Tyenne (tocilizumab-aazg)	March 2024	April (IV), July (SC) 2024
Enbrel (etanercept)	Erelzi (Etanercept-szzs)	August 2016	*April 2029*
	Eticovo (etanercept-ykro)	April 2019	*April 2029*
Humira (adalimumab)	**Amjevita (Adalimumab-atto)**	September 2016	January 2023
	Cyltezo (Adalimumab-adbm)	August 2017	July 2023
	Hyrimoz (adalimumab-adaz)	October 2018	October 2023
	Hadlima (adalimumab-bwwd)	July 2019	July 2023
	Abrilada (adalimumab-afzb)	November 2019	October 2023
	Hulio (adalimumab-fkjp)	July 2020	July 2023
	Yusimry (adalimumab-aqvh)	December 2021	July 2023
	Idacio (adalimumab-aacf)	December 2022	July 2023
	Yuflyma (adalimumab-aaty)	May 2023	July 2023
	Simlandi (adalimumab-ryvk)	February 2024	May 2024
	Adalimumab AbbVie	November 2023	

Autoimmune (cont.)*

Proper Name	Reference Products	Original Approval Date	Biosimilars
Insulin aspart	Fiasp	September 2017	
	Novolog	June 2000	
Insulin aspart protamine + insulin aspart	Novolog mix 50/50, 70/30	August 2008, November 2001	
Insulin degludec	Tresiba	September 2015	
Insulin degludec + insulin aspart	Ryzodeg 70/30	September 2015	
Insulin degludec + liraglutide	Xultophy 100/3.6	November 2016	
Insulin detemir	Levemir	June 2005	
Insulin glargine	Basaglar	December 2015	**Semglee (Insulin glargine-yfgn)**
	Lantus	April 2000	
	Semglee	June 2020	**Rezvoglar (insulin glargine-aglr)**
	Toujeo	February 2015	
Insulin glargine + lixisenatide	Soliqua 100/33	November 2016	
Insulin glulisine	Apidra	April 2004	
Insulin human	Afrezza	June 2014	
	Humulin R U-100, U-500	October 1982	
	Myxredlin	June 2019	
	Novolin R	June 1991	
Insulin isophane human	Humulin N	October 1982	
	Novolin N	July 1991	
Insulin isophane human + insulin human	Humulin 70/30	April 1989	
	Novolin 70/30	June 1991	
Insulin lispro	Admelog	December 2017	
	Humalog	June 1996	
	Lyumjev (lispro-aabc)	June 2020	
Insulin lispro protamine + insulin lispro	Humalog mix 50/50, 75/25	December 1999	

*Biologics

Autoimmune (cont.)

Reference Product	Biosimilar Name	Approval Date	Launch Date
Remicade (infliximab)	Inflectra (infliximab-dyyb)	April 2016	November 2016
	Renflexis (infliximab-abda)	May 2017	July 2017
	Ixifi (infliximab-qbtx)	December 2017	
	Avsola (infliximab-axxq)	December 2019	June 2020
	Zymfentra (biobetter)	October 2023	March 2024
Soliris (eculizumab)	**Bkemv (eculizumab-aeeb)**	May 2024	*March 2025*
	Epysqli (eculizumab-aagh)	July 2024	
Stelara (ustekinumab)	**Wezlana (ustekinumab-auub)**	October 2023	January 2025
	Selarsdi (ustekinumab-aekn)	April 2024	*February 2025*
	Pyzchiva (ustekinumab-ttwe)	June 2024	*February 2025*
	Otulfi (ustekinumab-aauz)	September 2024	*February 2025*
	Imuldosa (ustekinumab-srlf)	October 2024	*May 2025*
	Yesintek (ustekinumab-kfce)	November 2024	*February 2025*
	Steqeyma (ustekinumab-stba)	December 2024	*February 2025*
	Ustekinumab Alvotech IV	October 2024	*February 2025*
Tysabri (natalizumab)	Tyruko (natalizumab-sztn)	August 2023	

Oncology

Reference Product	Biosimilar Name	Approval Date	Launch Date
Avastin (bevacizumab)	Mvasi (Bevacizumab-awwb)	September 2017	July 2019
	Zirabev (bevacizumab-bvzr)	June 2019	December 2019
	Alymsys (bevacizumab-maly)	April 2022	October 2022
	Vegzelma (bevacizumab-adcd)	September 2022	March 2023
	Avzivi (bevacizumab-tnjn)	December 2023	
Herceptin (trastuzumab)	Ogivri (trastuzumab-dkst)	December 2017	December 2019
	Herzuma (trastuzumab-pkrb)	December 2018	March 2020
	Ontruzant (trastuzumab-dttb)	January 2019	April 2020
	Trazimera (trastuzumab-qyyp)	March 2019	February 2020
	Kanjinti (trastuzumab-anns)	June 2019	July 2019
	Hercessi (trastuzumab-strf)	April 2024	January 2025
Rituxan (rituximab)	Truxima (rituximab-abbs)	November 2018	November 2019
	Ruxience (rituximab-pvvr)	July 2019	January 2020
	Riabni (rituximab-arrx)	December 2020	January 2021

Ophthalmology

Reference Product	Biosimilar Name	Approval Date	Launch Date
Eylea (aflibercept)	**Yesafili (aflibercept-jbvf)**	May 2024	October 2024
	Opuviz (aflibercept-yszy)	May 2024	
	Ahzantive (aflibercept-mrbb)	June 2024	
	Pavblu (aflibercept-ayyh)	August 2024	
	Enzeevu (aflibercept-abzv)	August 2024	
Lucentis (ranibizumab)	**Byooviz (ranibizumab-nuna)**	September 2021	June 2022
	Cimerli (ranibizumab-eqrn)	August 2022	October 2022

Osteoporosis

Reference Product	Biosimilar Name	Approval Date	Launch Date
Prolia and Xgeva (denosumab)	**Jubbonti and Wyost (denosumab-bbdz)**	March 2024	*May 2025*

Supportive Care

Reference Product	Biosimilar Name	Approval Date	Launch Date
Epogen, Procrit (epoetin-alfa)	Retacrit (epoetin alfa-epbx)	May 2018	November 2018
Neulasta (pegfilgrastim)	Fulphila (pegfilgrastim-jmdb)	June 2018	July 2018
	Udenyca (pegfilgrastim-cbqv)	November 2018	January 2019
	Ziextenzo (pegfilgrastim-bmez)	November 2019	November 2019
	Nyvepria (pegfilgrastim-apgf)	June 2020	December 2020
	Fylnetra (pegfilgrastim-pbbk)	May 2022	May 2023
	Stimufend (pegfilgrastim-fpgk)	September 2022	February 2023
	Rolvedon (biobetter)	September 2022	October 2022
	Ryzneuta (biobetter)	November 2023	
Neupogen (filgrastim)	Zarxio (Filgrastim-sndz)	March 2015	September 2015
	Nivestym (filgrastim-aafi)	July 2018	September 2018
	Releuko (filgrastim-ayow)	February 2022	February 2022
	Nypozi (filgrastim-txid)	June 2024	December 2024

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Pipeline Biosimilars

Biosimilars in the Pipeline[12]

Autoimmune & Inflammatory:

- Actemra (tocilizumab)
- Cimzia (certolizumab)
- Enbrel (etanercept)
- Entyvio (vedolizumab)
- Humalog (insulin lispro)
- Humira (adalimumab)
- Lantus (insulin glargine)
- Novolog (insulin aspart)
- Simponi (golimumab)
- Soliris (eculizumab)
- Stelara (ustekinumab)
- Tysabri (natalizumab)
- Xolair (omalizumab)

Osteoporosis:

- Prolia and Xgeva (denosumab)

Oncology:

- Avastin (bevacizumab)
- Herceptin (trastuzumab)
- Rituxan (rituximab)

Ophthalmology:

- Eylea (aflibercept)
- Lucentis (ranibizumab)

Supportive Care:

- Epogen (epoetin-alfa)
- Neulasta (pegfilgrastim)
- Neupogen (filgrastim)

Reference Drug	Biosimilar	Manufacturer	Status	Estimated Launch
Actemra	CT-P47 (IV, SC)	Celltrion	Pending (01/2025)	TBD
	DRL TC (IV, SC)	Dr. Reddy's	Phase 3	TBD
	Tofidence (SC)	Biogen/Bio-Thera	Phase 1	TBD
Avastin	FKB238	Genetech; Roche	Pending	TBD
	Bmab-100	Biocon/Mylan/Viatris	CRL (2/9/24)	TBD
	Aybintio	Samsung Bioepis/Organon	Phase 3	TBD
	TRS003	TeRuisi	Phase 3	TBD
	HD204	Prestige Biopharma	Phase 3	TBD
Cimzia	XB003	Xbrane	Preclinical	TBD

Reference Drug	Biosimilar	Manufacturer	Status	Estimated Launch
Denosumab (Prolia®/Xgeva®)	AVT03	Alvotech/Alvogen	Phase 3	2025
	BP16	CuraTeQ/Aurobindo	Phase 3	2026
	Bmab 1000	Biocon	Phase 3	2025
	EB1001	JHL Biotech	Phase 3	2026
	ENZ215	Ezene/Alkem	Phase 3	2025
	MB09	Mabxience	Phase 3	2026
	MAB-22	Xentria/Meitheal	Phase 3	2028
	LY01011/LY06006	Luye Pharma Group	Phase 3	2026
	Stoboclo		Pending	2025
	Osenvelt		Pending	TBD
	FKS518	Amgen	Pending (03/2025)	TBD
	HLX14		Pending (3Q 2025)	TBD
	Olimab		Pending	2026
	Xbryk		Pending	TBD
	Obodence		Phase 1 (USA)	TBD
	TVB-009P		Pending (2H 2025)	TBD

Reference Drug	Biosimilar	Manufacturer	Status	Estimated Launch
Enbrel	YLB113	Lupin	Phase 3	2029
Eylea	CT-P42	Regeneron	Pending	2025 - 2027
	SCD411	Sam Chun Dang	Phase 3	2025-2032
	AVT06	Alvotech/Alvogen/Teva	Phase 3	2025-2032
	RBS-001	Rophibio/Amicogen	Phase 3	2025-2032
Entyvio	PB016	Polpharma	Phase 3	2027-2032
Herceptin	TX05	Roche; Genetech	Pending (01/2025)	2025
	HD201	Prestige BioPharma	Phase 3	2025-2026
Humalog	GL-LIS	Eli Lilly	Pending	TBD
Humira	Hadlima HC	AbbVie	Pending	TBD
	Yuflyma		Pending	TBD

Reference Drug	Biosimilar	Manufacturer	Status	Estimated Launch
Lantus Solostar	GL-GLA	Sanofi	Pending	TBD
Lucentis	Lucamzi Xlucane Ximluci	Xbrane/Bausch + Lomb/Bausch Health/Stada	CRL (4/21/24)	2025
	LUBT010	Lupin	Phase 3	2025-2026
Neulasta	Lapelga	Amgen	Pending	TBD
	Lupifil-P	Lupin	CRL (2/24)	CRL
	Fylnetra OBI; TPI-120	Amneal	Developing	TBD
	Stimufend OBI, MSB11455	Fresenius	Developing	2025-2026
Neupogen	Grastofil	Amgen	Pending	TBD
	Lupifil	Lupin	Phase 1	TBD
Novolog	AMP-004	Novo Nordisk	Pending	TBD
	GL-ASP		Pending	TBD
Ocrevus	CT-P53	Celltrion	Phase 3	TBD
Rituxan	DRL RI	Dr. Reddy's/Fresnius	CRL	CRL

Reference Drug	Biosimilar	Manufacturer	Status	Estimated Launch
Simponi	BAT2506	Bio-Thera	Phase 3	2025+
	AVT05	Alvotech/Teva	Phase 3	2H 2025+
Stelara	BAT2206	Johnson & Johnson (Janssen)	Pending (2Q 2025)	TBD
	Bmab1200		Pending (4Q 2024)	02/22/25
	CT-P43		Pending	03/07/25
Xolair	CT-P39	Celltrion	Pending (1Q 2025)	2026
	TEV-45779	Teva	Phase 3	2026+
	ADL-018	Kashiv/Amneal	Phase 3	2026+
	BP11	Phase 3	2H 2026	2027+

Conclusions

Advantages and Challenges[13]

Reduced Cost

- Lower baseline cost (10-15%) compared to reference products

Additional Treatment Options

- Expanded number of products to manage various complex and chronic diseases
- Medicare updates

Interchangeability

- Updated draft guidance → greater ability to substitute biosimilar products for reference products

Indication Extrapolation

- May be FDA approved for indications without direct biosimilar studies

Formulary Status

- Formularies may only cover select biosimilars, patients may be required to try/fail certain biosimilars before others
- Different cost-sharing for different products

Limited Availability

- Due to patent litigations, it may take many years for biosimilar products to enter the marketplace
- Biologic drug manufacturers are granted a 12-year exclusivity period

Adoption of Biosimilars

Requires FDA approval

- The FDA supports a competitive marketplace to improve patient access to medication and facilitate the reduction in healthcare costs

Adoption by healthcare institutions

- Formulary inclusion
- Dispensing of interchangeable products

Awareness and acceptance by **providers**

- As the number of available biosimilar and interchangeable products grow, providers will increasingly encounter patients taking a biosimilar product
- Patients seek information primarily from their healthcare providers as trusted sources on the safety and effectiveness of potential treatment options

Awareness and acceptance by **patients**

- Understanding patients' needs for information related to biosimilars can support conversations about biosimilars in the shared decision-making process

Key Takeaways

All biologics contain slight, natural variation as they are manufactured from living sources

- Biosimilar products must demonstrate no clinically meaningful differences in terms of safety and effectiveness compared to the reference product
- FDA-approved interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider (subject to state laws)

Availability and cost depends on clinical trials, formulary placement, and utilization management criteria

- Biosimilar products may not share every indication of the reference product
- Healthcare leaders play an important role in educating stakeholders to encourage use of biosimilars

Biosimilars and interchangeable biosimilars…

- Enable cost savings to the patient, payor, and the health system through greater access
- Provide more treatment options for patients for complex and chronic conditions
- Support market competition, which may help drive advancement among originator biologics

Resources

1. FDA: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars
    a. Biosimilar product information
    b. Healthcare provider materials
    c. Patient materials
2. Purple Book: https://purplebooksearch.fda.gov/
    a. Lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations
3. The Biosimilars Council: https://biosimilarscouncil.org/
    a. Toolkits for providers, patients, and insurers
4. Advisory committee materials for biosimilars
5. Provider materials

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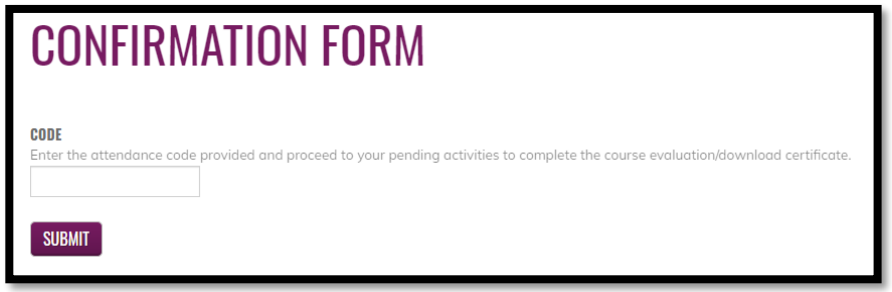

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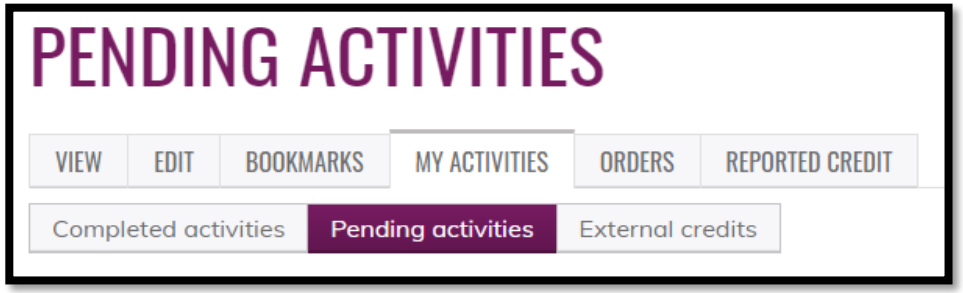

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Biosimilars: Updated Market Landscape

Hannah Rapp, PharmD