



**MONTHLY  
INJECTION**

March 9, 2026

### Latest News

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[Regeneron and Samsung Bioepis Settle EYLEA<sup>®</sup> BPCIA Litigations Related to Opuviz<sup>™</sup>](#)

[FDA Approves Accord's Neupogen<sup>®</sup> Biosimilar Filkri<sup>™</sup> \(filgrastim-laha\)](#)

[Court Dismisses Sandoz's Enbrel<sup>®</sup> \(etanercept\) Antitrust Lawsuit](#)

[Federal Circuit Reverses § 101 Unpatentability Finding for Gene Therapy Patent Asserted Against Elevidys<sup>®</sup>](#)

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### Spotlight On

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BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings and FDA-approvals for biologic drugs and related biosimilars, and an overview of the status of U.S. biosimilar patent litigations through February 28, 2026.

**Actemra<sup>®</sup>**  
(tocilizumab)

**Enbrel<sup>®</sup>**  
(etanercept)

**Herceptin<sup>®</sup>**  
(trastuzumab)

**Humira<sup>®</sup>**  
(adalimumab)

**Lantus<sup>®</sup> /  
Lantus<sup>®</sup> SoloSTAR<sup>®</sup>**  
(insulin glargine)

**Neulasta<sup>®</sup>**  
(pegfilgrastim)

**Prolia<sup>®</sup> / Xgeva<sup>®</sup>**  
(denosumab)

**Rituxan<sup>®</sup>**  
(rituximab)

**Biosimilar Litigation  
Dashboard**

## IPRs and PGRs

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- [Elevidys<sup>®</sup> \(delandistrogene moxeparvovec-rokl\)](#): On February 26, 2026, Sarepta filed a motion to withdraw IPR2026-00166 against Genzyme's U.S. Patent No. 12,298,313 as prematurely filed before the expiration of the nine-month period following issuance of the patent, and refiled the Petition as IPR2026-00270.

## Litigations

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- [Eylea<sup>®</sup> \(aflibercept\)](#): On February 11, 2026, Amgen and Samsung Bioepis settled Case Nos. 1:23-cv-00094 (N.D.W. Va.) and 1:23-cv-00106 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) and vacated the preliminary injunction previously entered by the Court. Under the settlement agreement, Samsung Bioepis can launch its Eylea<sup>®</sup> (aflibercept) interchangeable biosimilar Opuviz<sup>®</sup> (aflibercept-yszy) as early as January 2027.
- [Elevidys<sup>®</sup> \(delandistrogene moxeparvovec-rokl\)](#): On February 20, 2026, the Federal Circuit in CAFC Case No. 24-1408 reversed the District Court's grant of summary judgment of invalidity of REGENXBIO's U.S. Patent No. 10,526,617 asserted against Sarepta in Case No. 1:20-cv-01226 (D. Del.), finding that the patent was not directed to ineligible subject matter, and remanded for further proceedings.
- [Evenity<sup>®</sup> \(romosozumab-aqqg\)](#): On February 24, 2026, the Court entered summary judgment of invalidity of OssiFi-Mab's U.S. Patent Nos. 8,877,196, 11,608,373, and 11,807,681 asserted against Amgen in Case No. 1:23-cv-10861 (D. Mass.).

## aBLA Applications and FDA Activity

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- [Filkri<sup>™</sup> \(filgrastim-laha\)](#): On February 17, 2026, Accord BioPharma announced the January 2026 FDA approval of Filkri<sup>™</sup> (filgrastim-laha), a biosimilar of Amgen's Neupogen<sup>®</sup> (filgrastim).
- [DRL\\_AB \(abatacept\)](#): On February 20, 2026, Dr. Reddy's announced the FDA accepted its aBLA for DRL\_AB (abatacept), a proposed biosimilar of Bristol-Myers Squibb's Orencia<sup>®</sup> (abatacept), with a request for interchangeability. Dr. Reddy's previously announced the filing of the aBLA in December 2025.

## CDER Purple Book Updates

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- [Loargys<sup>®</sup> \(pegzilarginase-nbln\)](#): On February 23, 2026, the FDA approved Immedica Pharma's Loargys<sup>®</sup> (pegzilarginase-nbln).

## Non-U.S. Biosimilars / Follow-On Biologics

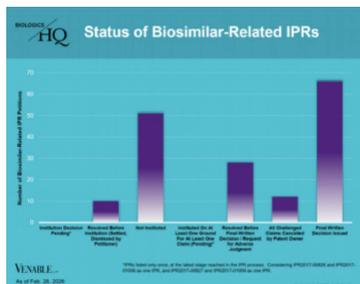
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- [Izambia / Denbrayce<sup>®</sup> \(denosumab-mobz\)](#): On February 5, 2026, HK inno.N / mAbxience announced the approval of Izambia / Denbrayce<sup>®</sup> (denosumab-mobz), biosimilars of Amgen's Prolia<sup>®</sup> / Xgeva<sup>®</sup> (denosumab), in South Korea.

- [Gotenfia \(golimumab\)](#): On February 13, 2026, STADA and Bio-Thera announced the approval of Gotenfia (golimumab), a biosimilar of Janssen / Johnson & Johnson's Simponi® (golimumab), in the E.U.
- [Ranluspec™ \(ranibizumab\)](#): On February 23, 2026, Lupin and Sandoz announced the approval of Ranluspec™ (ranibizumab), a biosimilar of Genentech's Lucentis® (ranibizumab), in the E.U.

## Statistics

### Status of Biosimilar-Related IPRs



### Biosimilars and Interchangeables Approved in the U.S.

ABLA No.	Reference Product	Biosimilar Name	ABLA Holder	CDER ID	Reference Product	Biosimilar Product	U.S. Approval Date
ABLA 70124	Amoxicillin	Amoxicillin-oral	Amgen	Top 20, 2016	Humana®	Abelva	Jan. 2023
ABLA 70108	Cytotec®	Adalimumab-ado	Roche/Genentech	Top 20, 2011	Humana®	Abelva	Jul. 2023
ABLA 70171	Humira®	Adalimumab-ado	Sandoz	Top 20, 2011	Humana®	Abelva	Jul. 2023
ABLA 70105	Humira®	Adalimumab-based	Sermorel Therapeutics	Top 20, 2011	Humana®	Abelva	Jul. 2023
ABLA 70118	Abelva®	Adalimumab-ado	Pfizer	Top 20, 2016	Humana®	Abelva	Oct. 2023
ABLA 70104	Humira®	Adalimumab-Rp	Novartis	Top 20, 2011	Humana®	Abelva	Jul. 2023
ABLA 70126	Humira®	Adalimumab-ado	Pharmacia	Top 20, 2011	Humana®	Abelva	Jul. 2023
ABLA 70125	Humira®	Adalimumab-ado	Cellgene	Top 20, 2011	Humana®	Abelva	Jul. 2023

### Biosimilar and Interchangeable Applications Pending in the U.S.

Biosimilar Name	Reference Product	ABLA Holder	Reference Product	Biosimilar Product	U.S. Status
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013
Humira®	Adalimumab	Amgen	Humana®	Abelva	Approved Jul. 2013

[View More Statistics](#)

## BiologicsHQ Search

Information contained in the Venable BiologicsHQ database relates to FDA-approved drug products listed in the CDER Purple Book. Product and Company page search results are reported for FDA-approved indications, aBLA and 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.

Enter Keywords

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