

MONTHLY INJECTION

July 9, 2026

Latest News

[FDA Approves Lupin's Ralvuspec™ \(ranibizumab-hkdz\) as Fourth Interchangeable Biosimilar of Lucentis®](#)

[aBLA Resubmissions: Xbrane's Xlucane \(ranibizumab\) and Alvotech's AVT05 \(golimumab\) and AVT06 \(aflibercept\)](#)

[Supreme Court Clarifies Standard for Pleading Inducement of Patent Infringement in Hikma v. Amarin](#)

[Keytruda Qlex™ Updates: PTAB Finds Additional Halozyme PH20 Patent Unpatentable in Final Written Decision](#)

[Alvotech Announces First FDA Acceptance of aBLA for Proposed Entyvio® Biosimilar – AVT16](#)

[Janssen Files BPCIA Litigation Against Alvotech's Proposed Simponi® / Simponi Aria® Biosimilar AVT05](#)

[Senate HELP Committee Advances Bills Addressing FDA / USPTO Disclosures and Biosimilar Interchangeability](#)

[Tanvex Receives Third CRL for Proposed Herceptin® Biosimilar TX-05](#)

[Read More News](#)

Spotlight On

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 June 30, 2026.

Actemra®
(tocilizumab)

Enbrel®
(etanercept)

Herceptin®
(trastuzumab)

Humira®
(adalimumab)

Lantus® /
Lantus® SoloSTAR®
(insulin glargine)

Neulasta®
(pegfilgrastim)

Prolia® / Xgeva®
(denosumab)

Rituxan®
(rituximab)

Biosimilar Litigation
Dashboard

IPRs and PGRs

- [Keytruda Qlex™ \(pembrolizumab; berahyaluronidase alfa-pmph\)](#):
 - On June 8, 2026, the PTAB issued a Final Written Decision in Merck's PGR2025-00004 against Halozyne's U.S. Patent No. 12,018,298 finding all challenged claims unpatentable for lack of written description and enablement.
 - On June 17, 2026, Halozyne filed a request for Director Review of the Final Written Decision in Merck's PGR2025-00006 finding all challenged claims of Halozyne's U.S. Patent No. 12,152,262 unpatentable.
 - On June 24, 2026, the PTAB issued a Final Written Decision in Merck's PGR2025-00009 against Halozyne's U.S. Patent No. 12,123,035 finding all challenged claims unpatentable for lack of written description and enablement.
- [Elevidys® \(delandistrogene moxeparvovec-rokl\)](#): On June 17, 2026, the PTAB Director denied Genzyme's request for Director Review of the decision instituting Sarepta's IPR2026-00150 without an opinion.

Litigations

- [Ajovy® \(fremanezumab-vfrm\)](#) / [Emgality® \(galcanezumab-gnlm\)](#): On June 17, 2026, Eli Lilly filed a request for an *en banc* rehearing in Appeal No. 24-1094, of the Federal Circuit's reversal of the grant of JMOL and reinstatement of the jury's verdict finding all challenged claims of Teva's patents valid and infringed in Case No. 1:18-cv-12029 (D. Mass.).
- [Perjeta® \(pertuzumab\)](#): On June 17, 2026, Genentech filed a notice of withdrawal of its ITC Complaint in ITC-337-3890 based on representations from Biocon that imported product was covered by 35 U.S.C. § 271(e)(1)'s safe harbor and that it did not have any U.S. commercialization agreements or discussions with U.S. distributors.
- [Simponi®](#) / [Simponi Aria® \(golimumab\)](#): On June 19, 2026, Janssen filed BPCIA Case No. 1:26-cv-01754 (E.D. Va.) against Alvotech alledging infringement of 14 patents by AVT05 (golimumab), a proposed biosimilar of Janssen's Simponi® / Simponi Aria® (golimumab).

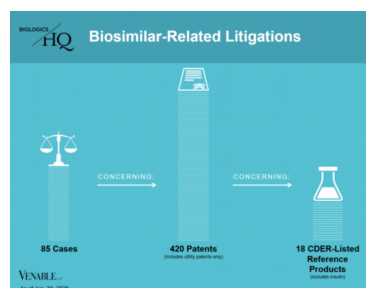
aBLA Applications and FDA Activity

- [Ranluspec™ \(ranibizumab-hkdz\)](#): On June 2, 2026, the FDA approved Lupin's Ranluspec™ (ranibizumab-hkdz) as an interchangeable biosimilar of Genentech's Lucentis® (ranibizumab).
- [Xlucane \(ranibizumab\)](#): On June 3, 2026, Xbrane announced the resubmission of its aBLA for Xlucane (ranibizumab), a proposed biosimilar of Genentech's Lucentis® (ranibizumab). The BsUFA (Biosimilar User Fee Act) target action date is set for October 29, 2026.
- [AVTo5 \(golimumab\)](#): On June 4, 2026, Alvotech and Teva announced the resubmission of an aBLA for AVTo5 (golimumab), a proposed biosimilar of Janssen's Simponi® / Simponi Aria® (golimumab).
- [AVTo6 \(aflibercept\)](#): On June 4, 2026, Alvotech and Teva announced the resubmission of an aBLA for AVTo6 (aflibercept), a proposed biosimilar of Regeneron's Eylea® (aflibercept).
- [AVT16 \(vedolizumab\)](#): On June 8, 2026, Alvotech and Teva announced the FDA acceptance of an aBLA for AVT16 (vedolizumab), with a request for interchangeability with Takeda's Entyvio® (vedolizumab).
- [TX-05 \(trastuzumab\)](#): On June 23, 2026, Tanvex announced the receipt of a Complete Response Letter from the FDA for TX-05 (trastuzumab), a proposed biosimilar of Genentech's Herceptin® (trastuzumab).

- [Lumvoa™ \(veligrotug-vvze\)](#): On June 26, 2026, the FDA approved Viridian Therapeutics' Lumvoa™ (veligrotug-vvze).
- [Tregzi™ \(allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq\)](#): On June 30, 2026, the FDA approved Orca Bio's Tregzi™ (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq).

- Zandoriah[®] (teriparatide): On June 15, 2026, CinnaGen announced the approval of Zandoriah[®] (teriparatide), a biosimilar of Eli Lilly's Forteo[®] (teriparatide), in the E.U.

Biosimilar-Related Litigations



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.

Contact the BiologicsHQ Team



Robert S. Schwartz, Ph.D.

Chair

+1 212.218.2298

RSchwartz@Venable.com



Ha Kung Wong

Partner

+1 212.218.2571

HWong@Venable.com

© 2026 Venable LLP. This email is published by the law firm Venable LLP. It is not intended to provide legal advice or opinion. Such advice may be given only when it is related to specific fact situations that Venable has accepted an engagement as counsel to address. ATTORNEY ADVERTISING.

[Venable.com](https://www.venable.com) | [Manage Preferences](#) | [Unsubscribe](#) | If you are having trouble viewing this email, [click here to view it in the browser](#) or contact us by mail at Venable LLP, 600 Massachusetts Avenue, NW, Washington, DC 20001.

