

Understanding Lymphoma Biosimilar Therapies

One type of treatment patients with lymphoma may receive is called a biologic therapy. Unlike most drugs, biologic therapies are produced in living organisms.^{1,2} The U.S. Food and Drug Administration (FDA) is the federal body responsible for closely monitoring and regulating drug manufacturing processes to protect public health, including the complicated process of producing biologics.²

What Is a Biosimilar?

A *biosimilar* is a biologic therapy that is modeled after an existing biologic therapy, or *reference product*, that has already been approved by the FDA. A biosimilar is expected to be just as effective as its reference product, but due to the complexities of making medications from natural sources, the two are not exactly the same. Manufacturers of biosimilars must show that minor differences in their chemical makeup do not change the safety and effectiveness of the biosimilar compared to the reference product.² Biosimilars should not be confused with generic drugs, which are chemically identical to the original branded drug after which they are modeled. The manufacturer of a generic drug must show that it is equivalent to the branded drug after which it is modeled.

FDA Review and Approval Process²

Gaining FDA approval for a biologic product is a complicated process. To ensure the safety and effectiveness of these therapies, they are first tested *in vitro* (outside the body), and sometimes in animals. A decision is then made as to whether drug testing can continue on to clinical trials with human participants. Results from many clinical trials must be presented to the FDA before a drug can receive approval. Although the process for approval of a biosimilar product is strict and time-consuming, it can often be made faster by comparing data with results from earlier clinical trials for its reference product. Because fewer lengthy and expensive clinical trials are required, the cost of treatment may be reduced.³



BIOSIMILARS IN LYMPHOMA

Biosimilars approved in the United States include therapies that stimulate or suppress the immune system, treat cancer, or lessen side effects of cancer treatments.⁴

Several biosimilars have been developed to treat patients with many types of cancer. Filgrastim-sndz (Zarxio) and filgrastim-aafi (Nivestym) are biosimilar therapies used for speeding up the recovery of white blood cell counts that have been depleted as a result of chemotherapy.⁵ Pegfilgrastim-jmdb (Fulphila) and pegfilgrastim-bmez (Ziextenzo) are longer-acting versions of

filgrastim that also speed up recovery of blood counts and could be used to decrease the chance of infection that is associated with some anti-cancer drugs.⁶ In the same way, epoetin alfa-epbx (Retacrit) is a biosimilar that is occasionally used to treat anemia following chemotherapy.⁷

Rituximab (Rituxan) is an FDA-approved biologic therapy widely used for treating patients with B-cell non-Hodgkin lymphomas (NHLs) and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).⁸

¹ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biological-therapy>

² <https://www.fda.gov/media/108557/download>

³ <https://www.cancercenter.com/community/blog/2018/12/whats-the-difference-biosimilar-and-generic-drugs>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6075809/>

⁴ <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>

⁵ Filgrastim-sndz PI Indications and Usage

⁶ Pegfilgrastim-jmdb pi Indications and Usage

⁷ Epoetin alfa-epbx PI Indications and Usage

⁸ https://www.nccn.org/professionals/physician_gls/pdf/ctl.pdf; Rituxan PI Indications and Usage

Patients interested in learning more about rituximab should view the *Immunotherapy* fact sheet on the Lymphoma Research Foundation's (LRF's) website at www.lymphoma.org/publications. Rituximab-abbs (Truxima) and rituximab-pvvr (Ruxience) are rituximab biosimilars that are approved by the FDA as single agents for *refractory* (disease does not respond to treatment) or *relapsed* (disease returns after treatment) low-grade or follicular B-cell NHL, and in combination with chemotherapy for previously untreated low-grade B-cell lymphomas.⁹ Rituximab-pvvr is also approved as part of a chemotherapy regimen for previously untreated diffuse large B-cell lymphoma (DLBCL) and CLL, and relapsed/refractory CLL. Rituximab-abbs or rituximab-pvvr may be substituted for rituximab, either as initial treatment or as subsequent treatment in relapsed/refractory disease.

TREATMENTS UNDER INVESTIGATION

Clinical trials are underway with biosimilar therapies such as IBI301 for NHL and DLBCL, ABP 798 for NHL, RTX83 for DLBCL, CT-P10 for follicular lymphoma (FL), and DRL_RI for FL.¹⁰

Questions to Ask Your Lymphoma Treatment Team

It is important to understand the benefits, risks, side effects, and cost differences of treatment options. Below are some questions that patients can ask their doctor when discussing treatment options.¹¹

- What subtype of lymphoma do I have?
- What treatment options are available for my particular subtype?
- Is biologic therapy an option?
- Is a biosimilar treatment or therapy available for my lymphoma, and is there a cost difference compared to other treatment options?
- What are the risks and side effects of a biosimilar treatment? Are they the same as the other treatments, and are there any activities, foods, or other medications that I should avoid while taking this treatment?
- Will my insurance cover the cost of a biosimilar treatment? What will my out-of-pocket costs be? How do the out-of-pocket costs compare to other treatment options?

LRF'S HELPLINE AND LYMPHOMA SUPPORT NETWORK

A lymphoma diagnosis often triggers a range of feelings and concerns. In addition, cancer treatment can cause physical discomfort. The LRF Helpline staff members are available to answer your general questions about a lymphoma diagnosis and treatment information, as well as provide individual support and referrals to you and your loved ones. Callers may request the services of a language interpreter. A part of the Helpline is LRF's one-to-one peer support programs, Lymphoma Support Network. This program connects patients and caregivers with volunteers who have experience with lymphomas, similar treatments, or challenges, for mutual emotional support and encouragement. You may find this useful whether you or a loved one is newly diagnosed, in treatment, or in remission.

MOBILE APP

Focus On Lymphoma is the first mobile application (app) that provides patients and caregivers comprehensive content based on their lymphoma subtype and tools to help manage their lymphoma such as, keep track of medications and blood work, track symptoms, and document treatment side effects. The *Focus On Lymphoma* mobile app is available for download for iOS and Android devices in the Apple App Store and Google Play. For additional information on the mobile app, visit FocusOnLymphoma.org. To learn more about any of these resources, visit our website at lymphoma.org, or contact the LRF Helpline at 800-500-9976 or helpline@lymphoma.org.

⁹ Rituximab-abbs PI Indications and Usage; rituximab-pvvr PI Indications and Usage

¹⁰ <https://clinicaltrials.gov/ct2/results?cond=lymphoma&term=biosimilar&cntry=&state=&city=&dist=> Page lists several clinical trials for rituximab biosimilars

¹¹ NHL Booklet p.48 Patient Tip box (Questions to Ask Before Treatment Begins)



GLOSSARY OF TERMS

Biologic therapies: Medicinal compounds produced in living cells by using biologic processes with modern technology

Clinical trials: Research studies to test the safety and effectiveness of drugs in people

FDA: The U.S. Food and Drug Administration is the federal body responsible for closely monitoring and regulating drug and biologic therapy manufacturing processes to protect public health

Highly similar therapy: A biosimilar product containing minor differences in chemical make-up compared with a reference product that does not alter clinical effectiveness or safety

Interchangeable therapy: A biosimilar product that can be used interchangeably with a reference product. Slight differences in its chemical make-up compared to the reference product are not expected to alter clinical effectiveness or safety

Relapse: Disease returns after treatment and/or a period of improvement

Refractory: Disease does not respond to treatment (meaning that the cancer cells continue to grow), or the response to treatment does not last very long

Resources

LRF offers a wide range of free resources that address treatment options, the latest research advances, and ways to cope with all aspects of lymphoma and CLL/SLL including our award-winning mobile app. LRF also provides many educational activities, including our in-person meetings, podcasts, webinars for people with lymphoma, as well as patient guides and e-Updates that provide the latest disease-specific news and treatment options. To learn more about any of these resources, visit our website at www.lymphoma.org, or contact the LRF Helpline at (800) 500-9976 or helpline@lymphoma.org.

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