



PRESS RELEASE

AbbVie's EPKINLY™ (epcoritamab injection/epcoritamab for injection) Receives Health Canada Authorization with Conditions as the First and Only Subcutaneous Bispecific Antibody to Treat Adult Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

MONTREAL, QC, October 17, 2023 – AbbVie (NYSE: ABBV), today announced that EPKINLY™ (epcoritamab injection/epcoritamab for injection) has received Health Canada authorization with conditions. It is the first and only subcutaneous (SC) T-cell engaging bispecific antibody for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL transformed from indolent lymphoma, high grade B-cell lymphoma (HGBCL), primary mediastinal B-cell lymphoma (PMBCL) or follicular lymphoma Grade 3B (FLG3b) after two or more lines of systemic therapy and who have previously received or are unable to receive CAR-T cell therapy.¹ EPKINLY has been issued marketing authorization with conditions, pending the results of clinical trials to verify its clinical benefit. EPKINLY is being co-developed by AbbVie and Genmab as part of the companies' oncology collaboration.

DLBCL is a type of aggressive, fast-growing non-Hodgkin's lymphoma (NHL), a cancer that develops in the lymphatic system and affects B cells, a type of white blood cell. DLBCL is the most common type of NHL. Although DLBCL is often curable, many patients are refractory to, or relapse after first-line treatment with standard chemoimmunotherapy.² For R/R patients, several targeted therapies including T-cell mediated treatments have recently emerged. However, convenient and readily-available subcutaneous single agent therapies or off-the-shelf treatment options are limited.^{1,2,3,4,5,6}

“As a non-chemotherapy, single-agent treatment, EPKINLY is a novel treatment option that fills an unmet need for Canadian patients with relapsed or refractory large B-cell lymphoma after at least two prior lines of therapy,” says Dr. John Kuruvilla, Hematologist in the Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre. “I am looking forward to being able to provide this treatment option to my patients and have confidence it will have a unique place in therapy.”

EPKINLY's authorization is based on the positive results of the EPCORE™ NHL-1 clinical trial (NCT03625037)¹⁰, in which EPKINLY delivered an overall response rate of 63 percent, a complete response rate of 39 percent and median duration of response of 12 months in heavily pretreated R/R DLBCL patients.¹

“DLBCL is an aggressive cancer type that can rapidly progress and resist treatment. Patients with RR DLBCL need innovative treatment options,” says Antonella Rizza, CEO, Lymphoma Canada. “Lymphoma Canada welcomes the authorization of epcoritamab and the hope it brings for patients living with RR DLBCL.”

“Health Canada's authorization of EPKINLY as a new treatment option with a novel mechanism of action for the treatment of third line DLBCL patients is an important milestone in our commitment to transforming standards of care for blood cancer patients through advancing our



innovative oncology pipeline to make a remarkable impact on the lives of Canadian patients,” says Tracey Ramsay, Vice President and General Manager, AbbVie Canada.

About the Health Canada Authorization

The Health Canada authorization is based on the data from the open-label, multi-cohort, multicenter, single-arm trial (EPCORE NHL-1; NCT03625037) conducted to evaluate EPKINLY, administered subcutaneously, as monotherapy in patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy. In this cohort (n=157), patients had received a median of 3 (range, 2 to 11) prior therapies, including 39% with prior chimeric antigen receptor (CAR) T-cell therapy (CAR-T). The majority (83%) had been refractory to their last therapy (29% refractory to CAR-T). The primary efficacy endpoint was overall response rate (ORR) determined by Lugano criteria (2014). Results showed an ORR of 63%. The median time to response (TTR) was 1.4 months and the median time to CR was 2.7 months. The median duration of response (mDOR) was 12.0 months.

About EPKINLY

EPKINLY is an IgG1-bispecific antibody created using Genmab's proprietary DuoBody® technology. Genmab's DuoBody-CD3 technology is designed to direct cytotoxic T cells selectively to elicit an immune response towards target cell types. It is designed to simultaneously bind to CD3 on T cells and CD20 on B-cells and induces T cell mediated killing of CD20+ cells.^{5,7,8,9} EPKINLY comes as a concentrate for solution, for SC injection, with each vial containing 4 mg in 0.8 mL (5 mg/mL) and a solution for SC injection, with each vial containing 48 mg in 0.8 mL (60 mg/mL) of epcoritamab.

AbbVie and Genmab continue to evaluate the use of epcoritamab as a monotherapy, and in combination, across lines of therapy in a range of hematologic malignancies. This includes three ongoing phase 3, open-label, randomized trials including a trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL (NCT 04628494) compared to investigator's choice chemotherapy, a phase 3 trial evaluating epcoritamab in combination with R-CHOP in adult participants with newly diagnosed DLBCL (NCT 05578976), and a phase 3, open-label clinical trial evaluating epcoritamab in combination in patients with R/R follicular lymphoma (FL) (NCT 05409066). Epcoritamab is not approved to treat newly diagnosed patients with DLBCL or FL. The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit clinicaltrials.gov for more information.

Please consult the EPKINLY™ Product Monograph at [abbvie.ca](https://www.abbvie.ca).

About AbbVie in Oncology

At AbbVie, we are committed to transforming standards of care for multiple blood cancers while advancing a dynamic pipeline of investigational therapies across a range of cancer types. Our dedicated and experienced team joins forces with innovative partners to accelerate the delivery of potentially breakthrough medicines. We are evaluating more than 20 investigational medicines in over 300 clinical trials across some of the world's most widespread and debilitating cancers. As we work to have a remarkable impact on people's lives, we are committed to exploring solutions to help patients obtain access to our cancer medicines.



About AbbVie

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas – immunology, oncology, neuroscience, and eye care – and products and services in our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow AbbVie Canada on X ([Twitter](#)), [Instagram](#) or find us on [LinkedIn](#).

-30-

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¹ Epkinly (epcoritamab injection/for injection) product monograph. AbbVie Corporation. Available at: <https://www.abbvie.ca/en/our-science/products.html>. October 2023.

² Sehn et al, 2020

³ What is Lymphoma. Lymphoma Coalition. <https://lymphomacoalition.org/what-is-lymphoma/>. Accessed April 24, 2023.

⁴ Kanas G, Ge W, Quek RGW, et al. *Leukemia & Lymphoma*. 2022;63(1):54-63.

⁵ Crump M, Neelapu SS, Farooq U, et al. *Blood*. 2017;130(16):1800-1808.

⁶ Chao MP. *Cancer Manag Res*. 2013;5:251-269.

⁷ Engelberts PJ, Hiemstra IH, de Jong B, et al. "DuoBody-CD3xCD20 induces potent T-cell-mediated killing of malignant B cells in preclinical models and provides opportunities for subcutaneous dosing." *EBioMedicine*. 2020;52:102625. DOI: 10.1016/j.ebiom.2019.102625.

⁸ Rafiq S, Butchar JP, Cheney C, et al. "Comparative Assessment of Clinically Utilized CD20-Directed Antibodies in Chronic Lymphocytic Leukemia Cells Reveals Divergent NK Cell, Monocyte, and Macrophage Properties." *J. Immunol*. 2013;190(6):2702-2711. DOI: 10.4049/jimmunol.1202588.

⁹ Singh V, Gupta D, Almasan A. "Development of Novel Anti-Cd20 Monoclonal Antibodies and Modulation in Cd20 Levels on Cell Surface: Looking to Improve Immunotherapy Response." *J Cancer Sci Ther*. 2015;7(11):347-358. DOI: 10.4172/1948-5956.1000373.

¹⁰ [EPCORE NHL-1 clinicaltrial.gov](https://clinicaltrials.gov/ct2/show/study/NCT02430431)