Incyte Announces Positive Topline Results from Pivotal Study of Tafasitamab (Monjuvi®/Minjuvi®) as a First-line Treatment for Diffuse Large B-Cell Lymphoma

January 5, 2026

- Phase 3 frontMIND trial evaluating the efficacy and safety of tafasitamab (Monjuvi®/Minjuvi®) and lenalidomide in addition to R-CHOP met its primary endpoint of progression-free survival (PFS)

- Based on these results, Incyte plans to file a supplemental Biologics License Application (sBLA) for tafasitamab and lenalidomide in addition to R-CHOP in first-line diffuse large B-cell lymphoma (DLBCL) in the first half of 2026

WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 5, 2026-- Incyte (Nasdaq:INCY) today announced positive topline results from the pivotal Phase 3 frontMIND trial evaluating the efficacy and safety of tafasitamab (Monjuvi®/Minjuvi®), a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody, and lenalidomide in addition to R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone) compared to R-CHOP alone as a first-line treatment for adults with newly diagnosed diffuse large B-cell lymphoma (DLBCL) with an International Prognostic Index (IPI) score of three to five (3-5) for patients >60 years of age, or age-adjusted IPI (aaIPI) of two to three (2-3) for patients ≤60 years of age.

The trial met its primary endpoint of progression-free survival (PFS) by investigator assessment (Hazard Ratio 0.75 [0.59,0.96]; *p*-value 0.019), according to Lugano 2014 criteria. The trial also met its key secondary endpoint of event-free survival (EFS) by investigator assessment. No new safety signals were observed.

“The frontMIND study results highlight the potential benefit of combining tafasitamab and lenalidomide with R-CHOP as an effective treatment option, offering the possibility of cures for more newly diagnosed DLBCL patients,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “Despite improvement in treatment for patients with DLBCL, outcomes for many high-risk patients are not optimal. We look forward to working with regulatory authorities globally and to providing a new treatment option for patients in the future.”

DLBCL is the most common type of non-Hodgkin lymphoma (NHL) in adults worldwide, representing 40% of all cases.[1] It is characterized as an aggressive, fast-growing type of lymphoma that can emerge in lymph nodes or extranodal sites such as the gastrointestinal tract, skin and brain.[2] Each year, approximately 24,000 people in the U.S. and up to 36,000 people in Europe are diagnosed with DLBCL.[3,4,5,6] With about 40% of these patients not responding to initial therapy or relapsing thereafter[7,8], there is a high medical need for new, effective therapies.

Based on these positive results, Incyte expects to file a supplemental Biologics License Application (sBLA) for tafasitamab for the first-line treatment of adults with newly diagnosed DLBCL in the first half of 2026. The frontMIND data will be submitted for presentation at an upcoming scientific meeting.

Tafasitamab was approved in combination with lenalidomide by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in 2020 and 2021 respectively, for adult patients with relapsed or refractory DLBCL not otherwise specified including DLBCL arising from low-grade lymphoma, and who are not eligible for autologous stem cell transplant. Additionally, tafasitamab was approved in combination with lenalidomide and rituximab by the FDA in June 2025 for adult patients with relapsed or refractory follicular lymphoma (FL). In November 2025, the EMA’s Committee for Medicinal Products for Human Use issued a positive opinion recommending the approval of tafasitamab for patients with relapsed or refractory FL.

About frontMIND

The frontMIND trial (NCT04824092) is a randomized, double-blind, placebo-controlled, global Phase 3 study in patients with previously untreated diffuse large B-cell lymphoma (DLBCL).

The study has enrolled approximately 900 adults (≥18 to ≤80 years) and is evaluating the efficacy and safety of tafasitamab and lenalidomide in addition to R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) compared with R-CHOP alone.

The primary endpoint of the study is investigator-assessed progression-free survival (PFS) using the Lugano 2014 criteria. Key secondary endpoints include event-free survival (EFS) by investigator assessment and overall survival (OS).

For more information about the frontMIND trial, please visit https://www.clinicaltrials.gov/study/NCT04824092.

About Tafasitamab (Monjuvi®/Minjuvi®)

Tafasitamab (Monjuvi®/Minjuvi®) is a humanized Fc-modified cytolytic CD19-targeting monoclonal antibody. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP). Incyte licenses exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc.

In the U.S., Monjuvi® (tafasitamab-cxix) is approved by the U.S. Food and Drug Administration in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

Additionally, Monjuvi received accelerated approval in the United States in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who

are not eligible for autologous stem cell transplant (ASCT).

In Europe, Minjuvi® (tafasitamab) received conditional Marketing Authorization from the European Medicines Agency in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory DLBCL who are not eligible for ASCT.

XmAb® is a registered trademark of Xencor, Inc.

Monjuvi, Minjuvi, the Minjuvi and Monjuvi logos and the “triangle” design are registered trademarks of Incyte.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of MONJUVI?

MONJUVI may cause serious side effects, including:

- Infusion reactions. Your healthcare provider will monitor you for infusion reactions during your infusion of MONJUVI. Tell your healthcare provider right away if you get fever, chills, flushing, headache, or shortness of breath during an infusion of MONJUVI.
- Low blood cell counts (platelets, red blood cells, and white blood cells). Low blood cell counts are common with MONJUVI, but can also be serious or severe. Your healthcare provider will monitor your blood counts during treatment with MONJUVI. Tell your healthcare provider right away if you get a fever of 100.4°F (38°C) or above, or any bruising or bleeding.
- Infections. Serious infections, including infections that can cause death, have happened in people during treatment with MONJUVI and after the last dose. Tell your healthcare provider right away if you get a fever of 100.4°F (38°C) or above, or develop any signs and symptoms of an infection.

The most common side effects of MONJUVI include:

- Feeling tired or weak
- Diarrhea
- Cough
- Fever
- Swelling of lower legs or hands
- Respiratory tract infection
- Decreased appetite

These are not all the possible side effects of MONJUVI. Your healthcare provider will give you medicines before each infusion to decrease your chance of infusion reactions. If you do not have any reactions, your healthcare provider may decide that you do not need these medicines with later infusions. Your healthcare provider may need to delay or completely stop treatment with MONJUVI if you have severe side effects.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before you receive MONJUVI, tell your healthcare provider about all of your medical conditions, including if you:

- Have an active infection or have had one recently.
- Are pregnant or plan to become pregnant. MONJUVI may harm your unborn baby. You should not become pregnant during treatment with MONJUVI. Do not receive treatment with MONJUVI in combination with lenalidomide if you are pregnant because lenalidomide can cause birth defects and death of your unborn baby.
- You should use an effective method of birth control (contraception) during treatment and for at least 3 months after your final dose of MONJUVI.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with MONJUVI.
- Are breastfeeding or plan to breastfeed. It is not known if MONJUVI passes into your breastmilk. Do not breastfeed during treatment for at least 3 months after your last dose of MONJUVI.

You should also read the lenalidomide Medication Guide for important information about pregnancy, contraception, and blood and sperm donation.

Tell your healthcare provider about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see the full Prescribing Information for Monjuvi, including Patient Information, for additional Important Safety Information.

About Incyte

A global biopharmaceutical company on a mission to *Solve On.*, Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia.

For additional information on Incyte, please visit Incyte.com or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether and when tafasitamab may provide a successful treatment option for patients with DLBCL and Incyte's plans to submit an sBLA in the first half of 2026, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA, EMA, and other regulatory authorities; the efficacy or safety of Incyte and its partners' products; the acceptance of Incyte and its partners' products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K and our quarterly report on Form 10-K for the quarter ended September 30, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1] Wang S. Epidemiology and etiology of diffuse large B-cell lymphoma. *Semin Hematol.* 2023 Nov;60(5):255-266.

[2] Skrabek P, et al. Emerging therapies for the treatment of relapsed or refractory diffuse large B cell lymphoma. *Current Oncology.* 2019 26(4): 253–265. doi.org/10.3747/co.26.5421.

[3] Siegel RL, et al. *CA Cancer J Clin*. 2020;70(1)7-30.

[4] Chihara D, et al. *Clin Lymphoma Myeloma Leuk*. 2022;22(12):e1092-e1099.

[5] Wang SS. *Semin Hematol*. 2023;60:255-256.

[6] GLOBOCAN 2020 Cancer Today.

[7] Swerdlow SH, et al. *Blood*. 2016;127(20):2375-2390.

[8] Kanas G, et al. *Leuk Lymphoma*. 2021;63:54-63.

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