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## **Incyte's Pivotal frontMIND Trial Showed Tafasitamab (Monjuvi®/Minjuvi®) Combination Significantly Prolonged Progression-free Survival, Reducing the Risk of Disease Progression or Death by 25% in Patients with Previously Untreated, High-risk DLBCL**

May 30, 2026

- *The Phase 3 frontMIND study evaluated tafasitamab (Monjuvi®/Minjuvi®) and lenalidomide in addition to R-CHOP, the current standard of care, compared with R-CHOP alone in patients with previously untreated high-risk diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL)*
- *Positive trends toward progression-free survival (PFS) benefit with tafasitamab and lenalidomide plus R-CHOP (Tafa-Len-R-CHOP) were observed across prespecified subgroups, including in patients with centrally confirmed lymphoma subtypes and both cell-of-origin (COO) molecular subtypes*
- *The frontMIND data support the submission of global regulatory applications for tafasitamab and lenalidomide added to R-CHOP for previously untreated DLBCL*
- *The data are being presented in an oral session at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in The Lancet\**

WILMINGTON, Del.--(BUSINESS WIRE)--May 30, 2026-- Incyte (Nasdaq:INCY) today announced positive 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 added to R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone; Tafa-Len-R-CHOP) versus R-CHOP alone as a first-line treatment for adults with previously untreated diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma (HGBL). Eligible patients had an International Prognostic Index (IPI) score of 3-5, or, for patients ≤60 years of age, an age-adjusted IPI (aaIPI) of 2-3.

The oral presentation of these data is taking place at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting being held May 29 – June 2, 2026, in Chicago (Abstract #LBA7000. Session: Oral Abstract Session – Hematologic Malignancies – Lymphoma and Chronic Lymphocytic Leukemia. May 30, 4:00 – 7:00 p.m. ET [3:00 – 6:00 p.m. CDT]) with simultaneous publication in *The Lancet*\*.

“The Phase 3 frontMIND results mark a potential inflection point in the treatment of patients with previously untreated, high-risk DLBCL and HGBL, where outcomes have remained largely unchanged for decades,” said Steven Stein, M.D., Executive Vice President, Chief Medical Officer and Head of Late-stage Development, Incyte. “These findings support Tafa-Len-R-CHOP as a potential new standard of care option in the first-line treatment of DLBCL, with benefit observed across both cell-of-origin (COO) molecular subtypes, and we look forward to advancing our global regulatory filings as we seek to bring this option to patients.”

The results build on [previously reported](#) topline data indicating the trial met its primary endpoint of progression-free survival (PFS) by investigator assessment.

The data demonstrate that Tafa-Len-R-CHOP resulted in a statistically significant and clinically meaningful improvement in PFS, with a 25% reduction in risk of disease progression or death among patients treated with Tafa-Len-R-CHOP compared with R-CHOP alone (HR 0.75 [P=0.0194]; 95% CI, 0.59–0.96; median follow-up of 35.2 months).

- A PFS increase of 8.2% was seen at 2 years (71.1% with Tafa-Len-R-CHOP vs 62.9% with R-CHOP).
- A PFS increase of 6.6% was seen at 3 years (67.3% with Tafa-Len-R-CHOP vs 60.7% with R-CHOP).
- Additionally, point estimates suggested trends toward PFS advantage with Tafa-Len-R-CHOP are broadly consistent across prespecified subgroups, including patients with centrally confirmed lymphoma subtypes and across COO molecular subtypes (ABC [Activated B-cell-like] and GCB [Germinal Center B-cell-like]).

Treatment with Tafa-Len-R-CHOP also significantly improved the key secondary endpoint of event-free survival (EFS) compared to R-CHOP alone (HR 0.79 [P=0.0260] 95% CI, 0.64-0.97; median follow-up of 35.4 months). Additionally, interim overall survival (OS) analysis demonstrated a positive trend toward improvement (HR=0.85 [P=0.2703] 95% CI, 0.63–1.14, median follow-up of 35.9 months), with final analysis planned after additional follow-up.

“For years, R-CHOP has remained the standard first-line therapy for DLBCL, yet nearly 40% of patients experience disease progression or relapse after initial treatment, underscoring the need for innovation,” said Dr. Georg Lenz, University Hospital Münster and principal investigator of the frontMIND study. “The frontMIND study shows that adding tafasitamab and lenalidomide to R-CHOP improved outcomes, including in patients with high-risk disease, who have historically faced poor prognoses and limited treatment options. These results suggest that this regimen could help broaden the first-line treatment options for this patient population.”

Tafa-Len-R-CHOP was generally well tolerated, and safety was consistent with the expected safety profile of adding Tafa-Len to R-CHOP.

The most common treatment-emergent adverse events (TEAEs) in the Tafa-Len-R-CHOP group were neutropenia (70.7%), anemia (46.3%) and peripheral neuropathy (40.6%). Any grade TEAEs were similar in both treatment arms (98.6% vs 97.1%). More Grade ≥3 TEAEs occurred with Tafa-Len-R-CHOP (86.7%) vs R-CHOP alone (76.1%). The most common Grade 3 TEAEs in the Tafa-Len-R-CHOP group were anemia (22.8%),

thrombocytopenia (13.1%) and neutropenia (12.4%). The most common Grade 3 TEAEs with R-CHOP alone were anemia (15.9%), febrile neutropenia (8.7%) and thrombocytopenia (6.7%).

Importantly, the incremental safety events observed with Tafa-Len-R-CHOP were well managed and did not interfere with the delivery of the R-CHOP backbone. Rates of TEAEs leading to discontinuation of all study treatment were similar between the two groups (5.2% for Tafa-Len-R-CHOP and 5.4% for R-CHOP alone). Although a higher rate of fatal TEAEs was observed with Tafa-Len-R-CHOP (5.9% vs 3.8% with R-CHOP), there were fewer overall deaths with Tafa-Len-R-CHOP (82 [18.5%]) compared to R-CHOP (97 [21.7%]), consistent with the positive trend observed in OS.

The frontMIND data support the submission of global regulatory applications for tafasitamab and lenalidomide in addition to R-CHOP for previously untreated DLBCL.

### **About Diffuse Large B-cell Lymphoma (DLBCL)**

Diffuse large B-cell lymphoma (DLBCL) is the most common type of non-Hodgkin lymphoma (NHL) in adults worldwide, representing 40% of all cases.<sup>1</sup> 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.<sup>2</sup> Each year, approximately 24,000 people in the U.S. and up to 36,000 people in Europe are diagnosed with DLBCL.<sup>3,4</sup> With about 40% of these patients not responding to initial therapy or relapsing thereafter,<sup>5,6</sup> there is a high medical need for new, effective therapies, particularly for high-risk patients.

### **About frontMIND**

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

The study enrolled 899 adults (≥18 to ≤80 years) and is evaluating the efficacy and safety of tafasitamab and lenalidomide added 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). 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).

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.

In Europe, Minjuvi® (tafasitamab) received conditional Marketing Authorization from the European Medicines Agency (EMA) 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. In addition, in December 2025, the EMA approved Minjuvi, in combination with lenalidomide and rituximab, for the treatment of adult patients with relapsed or refractory FL (Grade 1-3a) after at least one line of systemic therapy.

In Japan, Minjuvi is approved in combination with rituximab and lenalidomide for adult patients with relapsed or refractory follicular lymphoma (2L+ FL).

XmAb® is a registered trademark of Xencor, Inc.

Monjuvi and Minjuvi 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®**

Incyte is redefining what's possible in biopharmaceutical innovation. Through deep scientific expertise and a relentless focus on patients, we have built an established portfolio of first-in-class medicines and an extensive portfolio of next-generation medicines across our key franchises: Hematology, Oncology and Inflammation & Autoimmunity.

To learn more, visit [incyte.com](https://www.incyte.com) and [investor.incyte.com](https://investor.incyte.com). Follow us on social media: [LinkedIn](#), [X](#) and [Instagram](#).

#### **Incyte Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding whether and when tafasitamab may provide a successful treatment option for patients with DLBCL and HGBL, the potential and promise suggested by the Phase 3 frontMIND results, the potential for Tafa-Len-R-CHOP to become a new standard of care option in the first-line treatment of DLBCL, Incyte's plans to advance its global regulatory filings for tafasitamab and Incyte's aspirations and goals as set forth under the heading "About Incyte".

Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including Incyte's ability to demonstrate the efficacy and safety of its products and product candidates; the sufficiency of clinical trial data to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; Incyte's ability to achieve commercial success for its marketed products and product candidates, if approved; Incyte's ability to obtain and maintain protection of intellectual property for its products and technology; Incyte's reliance on third parties and partners; the acceptance of Incyte's products in the marketplace; market competition, sales, marketing, manufacturing and distribution requirements; and those risks and uncertainties discussed in greater detail in Incyte's reports filed with the U.S. Securities and Exchange Commission, including its annual report on Form 10-K and its quarterly report on Form 10-Q for the quarter ended March 31, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements.

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\*The Lancet publication is **embargoed until 3:00 p.m. CT (4:00 p.m. ET) on Saturday, May 30**. Post embargo link: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(26\)00866-4/fulltext \[thelancet.com\]](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(26)00866-4/fulltext [thelancet.com])

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

<sup>2</sup> 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](https://doi.org/10.3747/co.26.5421).

<sup>3</sup> Chihara D, et al. *Clin Lymphoma Myeloma Leuk*. 2022;22(12):e1092-e1099.

<sup>4</sup> GLOBOCAN 2020 Cancer Today.

<sup>5</sup> Swerdlow SH, et al. *Blood*. 2016;127(20):2375-2390.

<sup>6</sup> Kanas G, et al. *Leuk Lymphoma*. 2021;63:54-63.

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