Incyte Announces FDA Approval of Monjuvi® (tafasitamab-cxix) in Combination with Rituximab and Lenalidomide for Patients with Relapsed or Refractory Follicular Lymphoma

June 18, 2025

MONJUVI logo

- Monjuvi® (tafasitamab-cxix) in combination with rituximab and lenalidomide is the first FDA-approved CD19- and CD20-targeted immunotherapy combination for adult patients with follicular lymphoma (FL)

- Patients with relapsed or refractory FL achieved significantly improved progression-free survival with Monjuvi in combination with rituximab and lenalidomide in the Phase 3 registration trial

- This milestone represents the second approved indication for Monjuvi in the United States

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 18, 2025-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has approved Monjuvi® (tafasitamab-cxix), a humanized Fc-modified cytolytic CD19-targeting monoclonal antibody, in combination with rituximab and lenalidomide for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20250615896694/en/

"Patients living with relapsed or refractory FL have been waiting for new options that improve progression-free survival without substantial increase in side effects. Based on the data from the inMIND trial of Monjuvi, today's approval brings to this patient population the first CD-19 and CD20-targeted immunotherapy combination and a potential new treatment standard," said Hervé Hoppenot, Chief Executive Officer, Incyte. "This second U.S. approval for Monjuvi reinforces our commitment to advancing innovation for the lymphoma community."

The Priority Review and FDA approval of the supplemental Biologics License Application (sBLA) for Monjuvi was based on data from the pivotal, randomized, double-blind, placebo-controlled Phase 3 inMIND trial evaluating the efficacy and safety of Monjuvi in combination with rituximab and lenalidomide in adult patients with relapsed or refractory FL. Data from the trial was featured in the Late-breaking Session (LBA-1) at the 2024 American Society of Hematology (ASH) Annual Meeting.[1]

The study met its primary endpoint demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) by investigator assessment, which demonstrated 27.5% (N=273) of patients with an event in the Monjuvi group vs. 47.6% (N=275) of patients with an event in the control arm. Patients receiving Monjuvi in combination with rituximab and lenalidomide achieved a median PFS by investigator assessment of 22.4 months (95% CI, 19.2-not evaluable [NE]) compared to 13.9 months (95% CI, 11.5-16.4) in the control arm (hazard ratio [HR]: 0.43 [95% CI, 0.32-0.58]; P<0.0001). The PFS assessed by an Independent Review Committee (IRC) was consistent with investigator-based results. Median PFS by IRC was not reached (95% CI, 19.3-NE) in the Monjuvi group versus 16.0 months (95% CI, 13.9-21.1) in the control arm (HR: 0.41 [95% CI, 0.29-0.56]. The PFS benefit was consistent across prespecified patient subgroups, including number of previous lines of therapy.

The safety of Monjuvi in patients with FL was evaluated in 546 patients in the inMIND trial. Serious adverse reactions occurred in 33% of patients who received Monjuvi in combination with rituximab and lenalidomide, including serious infections in 24% of patients (including pneumonia and COVID-19 infection). Other serious adverse reactions in ≥ 2% of patients included renal insufficiency (3.3%), second primary malignancies (2.9%), and febrile neutropenia (2.6%). Fatal adverse reactions occurred in 1.5% of patients, including from COVID-19, sepsis, and adenocarcinoma. The most common adverse reactions (≥ 20%) in recipients of Monjuvi, excluding laboratory abnormalities, were respiratory tract infections (including COVID-19 infection and pneumonia), diarrhea, rash, fatigue, constipation, musculoskeletal pain, and cough. The most common Grade 3 or 4 laboratory abnormalities (≥ 20%) were decreased neutrophils and decreased lymphocytes.

"Follicular lymphoma is generally an indolent yet chronic cancer that frequently recurs after treatment, making long-term disease control a critical objective," said Christina Poh, M.D., Assistant Professor of Medicine at the University of Washington and Fred Hutchinson Cancer Center. "The FDA approval of Monjuvi in combination with rituximab and lenalidomide marks a significant advancement, offering a chemotherapy-free option that has demonstrated a meaningful reduction in the risk of disease progression across a broad patient population, including those with high-risk disease."

FL is the second most common type of non-Hodgkin lymphoma (NHL) and represents up to 30% of NHL cases.[2] While considered an indolent, slow-growing disease with prolonged survival, FL is challenging to treat due to its tendency for frequent relapse, need for multiple lines of therapy and potential transformation into large B-cell lymphoma.[2,3]

"While the initial responses to FL treatment are often positive, recurrence can become increasingly difficult for patients to manage as they navigate emotions and the next treatment steps related to relapse," said Mitchell Smith, M.D., Ph.D., Chief Medical Officer, Follicular Lymphoma Foundation. "We are pleased that the FDA has approved tafasitamab, part of a treatment combination offering a new option for patients living with this chronic disease."

In July 2020, Monjuvi in combination with lenalidomide received FDA approval 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). This indication was approved under accelerated approval by the U.S. FDA based on overall response rate (ORR). Continued approval of Monjuvi for this indication may be contingent on verification and description of clinical benefit in confirmatory trial(s).

Tafasitamab is also being evaluated as a therapeutic option in an ongoing pivotal trial for first-line DLBCL.

Incyte is committed to supporting patients and removing barriers to access medicines. Eligible patients in the U.S. who are prescribed Monjuvi have access to IncyteCARES (Connecting to Access, Reimbursement, Education and Support), a comprehensive program offering personalized patient support, including financial assistance and ongoing education and additional resources. More information about IncyteCARES is available by visiting www.incytecares.com or calling 1-855-452-5234, Monday through Friday, from 8 a.m. to 8 p.m. ET.

About inMIND

A global, double-blind, randomized, controlled Phase 3 study, inMIND (NCT04680052) evaluated the efficacy and safety of tafasitamab in combination with rituximab and lenalidomide compared with placebo in combination with rituximab and lenalidomide in patients with relapsed or refractory follicular lymphoma (FL) Grade 1 to 3a or relapsed or refractory nodal, splenic or extranodal marginal zone lymphoma (MZL). The study enrolled a total of 654 adults (age ≥18 years).

The primary endpoint of the study is progression-free survival (PFS) by investigator assessment in the FL population, and the key secondary endpoints are PFS in the overall population as well as positron emission tomography complete response (PET-CR) and overall survival (OS) in the FL population.

For more information about the study, please visit https://clinicaltrials.gov/study/NCT04680052.

About Monjuvi® (tafasitamab-cxix)

Monjuvi® (tafasitamab-cxix) is a humanized Fc-modified cytolytic CD19-targeting monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. 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). MorphoSys and Incyte entered into: (a) in January 2020, a collaboration and licensing agreement to develop and commercialize tafasitamab globally; and (b) in February 2024, an agreement whereby Incyte obtained exclusive rights to develop and commercialize tafasitamab globally.

In the U.S., Monjuvi 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, rash, 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 or symptoms of an infection

The most common side effects of MONJUVI when given with lenalidomide in people with DLBCL include:

- respiratory tract infection
- feeling tired or weak
- diarrhea
- cough
- fever
- swelling of lower legs or hands
- decreased appetite

The most common side effects of MONJUVI when given with lenalidomide and rituximab in people with FL include:

- respiratory tract infections
- diarrhea
- rash
- feeling tired or weak
- muscle and bone pain
- constipation
- cough

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.

Before you receive MONJUVI, tell your healthcare provider about all 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 3 months after your last dose of MONJUVI
    - Tell your healthcare provider right away if you become pregnant or think 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 and 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.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Incyte Medical Information at 1-855-463-3463.

Please see the full Prescribing Information including the Medication Guide for Monjuvi.

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 Monjuvi may provide a successful treatment option for patients with FL, 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 and other regulatory authorities outside of the United States; 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 Incyte's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2024 and its quarterly report on form 10Q for the quarter ended March 31, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Sehn L H., et al. ASH Annual Meeting 2024; Late Breaking Abstract Tafasitamab Plus Lenalidomide and Rituximab for Relapsed or Refractory Follicular Lymphoma: Results from a Phase 3 Study (inMIND).

[2] National Center for Biotechnology Information. Follicular Lymphoma. https://www.ncbi.nlm.nih.gov/books/NBK538206/. Accessed March 7, 2025.

[3] G. Gupta, et al. Am J Blood Res. 2022 Aug 15;12(4):105–124.

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