Incyte Announces European Commission Approval of Minjuvi® (tafasitamab) for the Treatment of Relapsed or Refractory Follicular Lymphoma

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- *Minjuvi® (tafasitamab) in combination with lenalidomide and rituximab is the first CD19- and CD20-dual-targeted immunotherapy combination regimen approved for eligible patients in Europe with relapsed or refractory FL*
- *Patients with relapsed or refractory FL achieved significantly improved progression-free survival with Minjuvi in combination with rituximab and lenalidomide in the Phase 3 inMIND registration trial*
- *In Western countries, including Europe, relapsed or refractory FL affects 2-4 out of every 100,000 people*[1]

WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 17, 2025-- Incyte (Nasdaq:INCY) today announced that the European Commission (EC) has approved Minjuvi® (tafasitamab) in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) (Grade 1-3a) after at least one line of systemic therapy.

"The EC approval of Minjuvi addresses a critical need, bringing a new, first-of-its-kind, chemotherapy-free option to patients in Europe with relapsed or refractory FL," said Bill Meury, President and Chief Executive Officer, Incyte. "Historically, FL patients have had limited treatment options in the second-line setting, and we are proud to drive this important advancement for the lymphoma community as we seek to deliver innovative medicines for patients with cancer."

The EC decision follows the positive opinion received from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) in November 2025. This marks the second indication for Minjuvi, which was previously approved by the EC in combination with lenalidomide for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

The EC decision is based on data from the Phase 3 inMIND trial evaluating the efficacy and safety of Minjuvi in combination with rituximab and lenalidomide as a treatment for patients with relapsed or refractory FL. Results from the trial showed that Minjuvi combined with rituximab and lenalidomide met its primary endpoint. The data demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) in comparison to placebo added to lenalidomide and rituximab. Patients receiving Minjuvi 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 Minjuvi group versus 16.0 months (95% CI, 13.9-21.1) in the placebo group (HR: 0.41 [95% CI, 0.29-0.56].

Minjuvi was generally well-tolerated, with a manageable safety profile. Safety and tolerability were comparable with the addition of tafasitamab to lenalidomide in combination with rituximab. The most common adverse reactions in the Phase 3 study (≥20%) in recipients of Minjuvi, excluding laboratory abnormalities, were respiratory tract infections (including COVID-19 infection and pneumonia), diarrhea, rash, fatigue, constipation, musculoskeletal pain and cough.[2]

FL is the most common slow-growing form of B-cell non-Hodgkin lymphoma (NHL), representing about 30% of NHL cases globally. It is considered incurable, with patients frequently relapsing after initial therapy and experiencing a progressively worsening prognosis with each recurrence.[3] Despite advances in treatment, there remains a significant unmet need for additional options for relapsed or refractory FL, with approximately 2-4 out of every 100,000 people affected in Western countries.[1]

"Relapsed or refractory FL is an incurable, complex and persistent cancer," said Stefano Luminari, M.D., Professor of Oncology, University of Modena and Reggio Emilia, Italy and inMIND study investigator. "The EC approval of Minjuvi in combination with lenalidomide and rituximab represents an important innovation, as it brings the first CD19- and CD20-dual-targeted immunotherapy to eligible patients with FL in Europe, which has demonstrated a meaningful reduction in the risk of disease progression, including among those with high-risk disease."

About inMIND
A global, double-blind, randomized, placebo-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 Minjuvi® (tafasitamab)
Minjuvi® (tafasitamab) 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 mechanisms 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 U.S. 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 the European Union, Minjuvi also 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.

Safety Information from the EU Summary of Product Characteristics (SmPC)
Minjuvi should be administered to patients with an active infection only if the infection is treated appropriately and well controlled. Patients with a history of recurring or chronic infections may be at increased risk of infection and should be monitored appropriately. Patients should be advised to contact their healthcare professionals if fever or other evidence of potential infection, such as chills, cough or pain on urination, develops.

Treatment with Minjuvi in combination with lenalidomide and/or rituximab should not be initiated in female patients unless pregnancy has been excluded.

In the inMIND study, the most common adverse reactions were infections (68%), including viral infections (41%) and bacterial infections (27%); neutropenia (57%), rash (36.4%), asthenia (34.9%), pyrexia (19%), thrombocytopenia (17%), anaemia (17%), infusion related reaction (15.9%), pruritus (15.6%), and headache (10.4%).

The most common serious adverse reactions were infections (26%), including viral infections (13%) and bacterial infections (6%), febrile neutropenia (2.8%), and pyrexia (1.8%).

Treatment with tafasitamab can cause serious or severe myelosuppression including neutropenia, thrombocytopenia, and anaemia. Complete blood counts should be monitored throughout treatment and prior to administration of each treatment cycle.

For more information, see the Minjuvi SmPC.

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.

Forward-Looking Statements
Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the potential offered by Minjuvi, contain predictions, estimates, and other forward-looking statements. These statements are based on Incyte’s current expectations and are subject to risks and uncertainties that may cause actual results to differ materially.

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 EC, FDA 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 Incyte's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K and its report on Form 10-Q for the quarter ended September 30, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1] Zinzani P.L., Muñoz J., Trotman J. (2024) Current and future therapies for follicular lymphoma. *Exp Hematol Oncol*, 13(1):87. Link to source (https://pmc.ncbi.nlm.nih.gov/articles/PMC11340193/)

[2] 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). Link to source (https://ash.confex.com/ash/2024/webprogram/Paper212970.html)

[3] Dreyling M., Ghielmini M., Rule S., et al. (2021) Newly diagnosed and relapsed follicular lymphoma: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. *Ann Oncol*, 32(3):298-308. Link to source (https://pubmed.ncbi.nlm.nih.gov/33249059/)

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