Incyte Japan Announces Approval of Minjuvi® (tafasitamab) in Combination with Rituximab and Lenalidomide for the Treatment of Relapsed or Refractory Follicular Lymphoma

December 22, 2025

TOKYO--(BUSINESS WIRE)--Dec. 22, 2025-- Incyte Biosciences Japan G.K. today announced approval from Japan's Ministry of Health, Labour and Welfare (MHLW) for Minjuvi® (tafasitamab) in combination with rituximab and lenalidomide for adult patients with relapsed or refractory follicular lymphoma (2L+ FL).

"Today's approval of Minjuvi in combination with rituximab and lenalidomide marks a significant milestone as the first dual-targeted CD19 and CD20 immunotherapy combination for relapsed or refractory FL in Japan," said Yasuyuki Ishida, General Manager, Incyte Biosciences Japan. "By improving progression-free survival, Minjuvi offers a chemotherapy-free option for eligible patients with relapsed or refractory disease. This approval underscores our commitment to bridging critical treatment gaps to patients and families affected by this challenging disease in Japan."

The approval is based on the pivotal Phase 3 inMIND trial, which enrolled 654 adult patients, including patients based in Japan. The study demonstrated that Minjuvi combined with rituximab and lenalidomide significantly improved progression-free survival (PFS) compared to the control arm.[1] Patients receiving Minjuvi achieved a median PFS of 22.4 months, significantly longer than the 13.9 months observed in the control arm.[1] The hazard ratio was 0.43, with a p-value of less than 0.0001, indicating a substantial reduction in the risk of progression.[1]

Assessments by an Independent Review Committee confirmed these results, with median PFS not reached in the Minjuvi group, compared to 16.0 months in the placebo group.[1] Minjuvi was generally well-tolerated, with respiratory infections, diarrhea and fatigue among the most common adverse reactions.[1]

FL is the second most common, slow-growing form of B-cell non-Hodgkin lymphoma (NHL) in Japan, accounting for 13.5% of all NHL types.[2] It is considered incurable, and approximately 20% of patients experience progression or relapse within the first two years of starting treatment. This early progression (POD24) is associated with a significantly poorer prognosis, with only 34–50% of these patients being alive at five years.[3,4,5] Despite advances in treatment, there remains a significant unmet need for additional options for relapsed or refractory FL.

This is the first regulatory approval for Minjuvi in Japan.

About inMIND
The inMIND study (NCT04680052) is a global, double-blind, randomized, placebo-controlled Phase 3 study evaluating 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).[6]

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.[6]

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 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 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 Europe, Minjuvi 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. 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.

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
Please refer to the Minjuvi Product Information (PI) for precautions concerning indications, dosage and administration and safety information in Japan, Japan Pharmaceuticals and Medical Devices Agency.

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.

Incyte Biosciences Japan G.K. is a wholly owned subsidiary of Incyte. For more information on Incyte in Japan, visit www.incyte.jp.

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 the potential for tafasitamab, in combination with rituximab and lenalidomide, to become a new treatment option for relapsed or refractory follicular lymphoma, 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 MHLW, 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-Q for the quarter ended September 30, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Sehn L H, Luminari S, Scholz CW, 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] Toth J A, Rahshenas M, Nowacki G, et al. A descriptive analysis of real-world oncology biosimilar use in Japan. 2024. Future Oncol. 2024;20: 1837-1850.

[3] Carbone A, Roulland S, Gloghini A, et al. Follicular lymphoma. Nat Rev Dis Primers. 2019;5:83.

[4] Casulo C, Nastoupil L, Fowler NH, et al. Unmet needs in the first-line treatment of follicular lymphoma. Ann Oncol. 2017;28:2094-2106.

[5] Wagner-Johnston ND, Link BK, Byrtek M, et al. Outcomes of transformed follicular lymphoma in the modern era: a report from the National LymphoCare Study (NLCS). Blood. 2015;126:851-857.

[6] ClinicalTrials.gov. A phase 3 study to assess efficacy and safety of tafasitamab plus lenalidomide and rituximab compared to placebo plus lenalidomide and rituximab in patients with relapsed/refractory (r/r) follicular lymphoma or marginal zone lymphoma. (InMIND). Available at https://clinicaltrials.gov/study/NCT04680052. Accessed November 2025.

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Incyte Contacts:
Media
media@incyte.com

Investors
ir@incyte.com

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