# Incyte Japan Announces Approval of Minjuvi® (tafasitamab) in Combination with Lenalidomide for the Treatment of Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

June 19, 2026

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 19, 2026-- Incyte Biosciences Japan G.K. today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved Minjuvi® (tafasitamab) in combination with lenalidomide for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

"This approval provides a new option for patients in Japan living with relapsed or refractory DLBCL, an aggressive disease with historically limited treatment options," said Yasuyuki Ishida, General Manager, Incyte Biosciences Japan. "We are committed to helping address critical unmet needs for patients and their families affected by this challenging cancer."

DLBCL is the most common subtype of non-Hodgkin lymphoma and is an aggressive malignancy of B lymphocytes. While many patients respond to initial therapy, outcomes remain poor for those with relapsed or refractory disease, particularly for patients who are not eligible for autologous stem cell transplant.[1]

The approval is based on results from the MOR208C203 Trial: L-MIND (NCT02399085), an international Phase II trial, and INCMOR 0208-102 Trial Part 4 (Group 6): J-MIND (NCT04661007), a domestic Phase Ib/II trial in Japan, both of which evaluated the safety and efficacy of Minjuvi in combination with lenalidomide in patients with relapsed or refractory DLBCL who are not eligible for autologous stem cell transplant (ASCT).[2,4] In the L-MIND trial, based on an independent review committee assessment (data cutoff date: November 20, 2018), the overall response rate (ORR) was 58.8% (primary endpoint), with a complete response (CR) rate of 41.3% and a partial response (PR) rate of 17.5%.[3] The median duration of response (mDOR) had not been reached at a median follow-up of 44 months or more.[3] Furthermore, based on the independent review committee's assessment in the J-MIND trial (data cutoff date: August 31, 2023), the response rate was 71.4%, with a complete response (CR) rate of 45.2% and a partial response (PR) rate of 26.2%.[4] The main adverse events included neutropenia and thrombocytopenia.[4,5] Overall, Minjuvi in combination with lenalidomide demonstrated a clinically meaningful response, and the side effects were manageable.[4,5]

This approval represents the second regulatory approval for Minjuvi in Japan. Minjuvi in combination with rituximab and lenalidomide was previously approved by the MHLW for the treatment of adult patients with relapsed or refractory follicular lymphoma (2L+ FL).

**About L-MIND**
L-MIND was a single-arm, open-label Phase 2 study evaluating tafasitamab in combination with lenalidomide in adults with relapsed or refractory diffuse large B-cell lymphoma who had received at least one, but no more than three, prior lines of therapy (including an anti-CD20 therapy such as rituximab) and who were not eligible for, or refused, high-dose chemotherapy followed by autologous stem cell transplant.[2] The primary endpoint was overall response rate; secondary endpoints included duration of response, progression-free survival, and overall survival.[2]

For more information about the study, please visit https://clinicaltrials.gov/study/NCT02399085.

**About J-MIND**
J-MIND Trial Part 4 (Group 6) (NCT04661007) is a Japanese Phase Ib/II clinical trial evaluating the efficacy and safety of tafasitamab in combination with lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Patients enrolled in this trial had received one to three prior systemic therapies, including CD20-targeted therapy, and were deemed by the principal investigator to be ineligible for or unresponsive to autologous hematopoietic stem cell transplantation.[4]

The primary endpoint of this trial was the objective response rate (ORR) as assessed by an independent review committee based on the Lugano criteria; secondary endpoints included complete response (CR), progression-free survival (PFS), and overall survival (OS).[4]

For more information about the study, please visit https://clinicaltrials.gov/study/NCT04661007.

**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) 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).[6] Additionally, Monjuvi is approved by the U.S. FDA in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).[6]

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.[7] Additionally, Minjuvi is approved 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 in Europe.[7]

In Japan, Minjuvi is approved in combination with lenalidomide for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma

(DLBCL) in Japan.[8] Minjuvi is also 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**
Please refer to the Minjuvi Product Information (PI) for indications, dosage and administration, precautions, and safety information in Japan, as well as the Pharmaceuticals and Medical Devices Agency (PMDA) website.

**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 and Investor.Incyte.com. Follow us on social media: LinkedIn, X and Instagram.

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**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 the potential for Minjuvi to provide a new treatment option for patients in Japan with DLBCL, 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; and sales, marketing, manufacturing, and distribution requirements, as well as the 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 for the year ended December 31, 2025 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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[8] Incyte. Minjuvi® (tafasitamab) Product Information (Japan) and Pharmaceuticals and Medical Devices Agency (PMDA) electronic package insert. Accessed June 2026. Link to source (https://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html).

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**Incyte Contacts:**

**Media**
media@incyte.com

**Investors**
ir@incyte.com

Source: Incyte Biosciences Japan G.K.