



Media Release

National Comprehensive Cancer Network® Updates Designation of Monjuvi® (tafasitamab-cxix) to Preferred Regimen in its Clinical Practice Guidelines in Oncology for B-cell Lymphomas

BOSTON, Mass., USA – March 15, 2022 – MorphoSys U.S. Inc., a fully owned subsidiary of MorphoSys AG (FSE: MOR; NASDAQ: MOR), announced today that the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) in Oncology for B-cell Lymphomas have been updated, and the designation for Monjuvi® (tafasitamab-cxix) in combination with lenalidomide is now a Preferred Regimen for second-line therapy in patients with Diffuse Large B-cell Lymphoma (DLBCL) who are not candidates for transplant.

“Updates to NCCN Guidelines are made periodically when additional efficacy and safety data are available, providing current information on the use of cancer therapies,” said Joe Horvat, U.S. General Manager, MorphoSys. “Monjuvi is a targeted immunotherapy that addresses an immediate medical need for certain adult patients living with Diffuse Large B-cell Lymphoma. We are gratified the NCCN panel acknowledged the additional data submitted for Monjuvi and updated the designation of Monjuvi in combination with lenalidomide to a Preferred Regimen in its Clinical Practice Guidelines in Oncology.”

In July 2020, the U.S. Food and Drug Administration (FDA) approved Monjuvi in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate (ORR) from the one-year primary analysis of the L-MIND study. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). In the U.S., Monjuvi is the only approved second-line targeted immunotherapy for this patient population.

The NCCN is a not-for-profit alliance of 30 leading cancer centers devoted to patient care, research, and education. The intent of the NCCN Guidelines is to assist in the decision-making process of individuals involved in cancer care – including physicians, nurses, pharmacists, payers, patients, and their families – with the ultimate goal of improving patient care and outcomes. The updated NCCN Guidelines are available at www.nccn.org.

NCCN® and the NCCN Guidelines® are registered trademarks of National Comprehensive Cancer Network.

About Diffuse Large B-cell Lymphoma (DLBCL)

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide, characterized by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs.¹ It is an aggressive disease with about 40% of patients not responding to initial therapy or relapsing thereafter, leading to a high medical need for new, effective therapies, especially for patients who are not eligible for an autologous stem cell transplant in this setting.²

About Monjuvi (tafasitamab-cxix)

Tafasitamab is a humanized Fc-modified cytolytic CD19 targeted immunotherapy. 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).

In the United States, Monjuvi (tafasitamab-cxix) is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low-grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Europe, Minjuvi® (tafasitamab) received conditional marketing authorization in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

Monjuvi and Minjuvi are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi in the U.S., and marketed by Incyte under the brand name Minjuvi in the EU.

XmAb® is a registered trademark of Xencor, Inc.

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 treatments 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.

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 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 MorphoSys

At MorphoSys, we are driven by our mission to give more life for people with cancer. As a global commercial-stage biopharmaceutical company, we use groundbreaking science and technologies to discover, develop, and deliver innovative cancer medicines to patients. MorphoSys is headquartered in Planegg, Germany, and has its U.S. operations anchored in Boston, Massachusetts. To learn more, visit us at www.morphosys.com and follow us on [Twitter](#) and [LinkedIn](#).

MorphoSys Forward-looking Statements

This communication contains certain forward-looking statements concerning the MorphoSys group of companies, including the expectations regarding Monjuvi's ability to treat patients with relapsed or refractory diffuse large B-cell lymphoma, the further clinical development of tafasitamab-cxix, including ongoing confirmatory trials, additional interactions with regulatory authorities and expectations regarding future regulatory filings and possible additional approvals for tafasitamab-cxix as well as the commercial performance of Monjuvi. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements contained herein represent the judgment of MorphoSys as of the date of this release and involve known and unknown risks and uncertainties, which might cause the actual results, financial condition and liquidity, performance or achievements of MorphoSys, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if MorphoSys' results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are MorphoSys' expectations regarding risks and uncertainties related to the impact of the COVID-19 pandemic to MorphoSys' business, operations, strategy, goals and anticipated milestones, including its ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products, the global collaboration and license agreement for tafasitamab, the further clinical development of tafasitamab, including ongoing confirmatory trials, and MorphoSys' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials, additional interactions with regulatory authorities and expectations regarding future regulatory filings and possible additional approvals for tafasitamab-cxix as well as the commercial performance of Monjuvi, MorphoSys' reliance on collaborations with third parties, estimating the commercial potential of its development programs and other risks indicated in the risk factors included in MorphoSys' Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. MorphoSys expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

References:

1. Sarkozy C, et al. Management of relapsed/refractory DLBCL. Best Practice Research & Clinical Haematology. 2018 31:209-16. doi.org/10.1016/j.beha.2018.07.014.
2. 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.

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