



## Incyte and MorphoSys Announce First Patient Dosed in Phase 3 frontMIND Study Evaluating Tafasitamab Combination as a First-Line Treatment for Diffuse Large B-Cell Lymphoma

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PLANEGG, Germany & MUNICH & WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (NASDAQ:INCY) and MorphoSys AG (FSE:MOR; NASDAQ:MOR) today announced that the first patient has been dosed in the pivotal Phase 3 *frontMIND* study evaluating tafasitamab and lenalidomide in addition to rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) compared to R-CHOP alone as first-line treatment for high-intermediate and high-risk patients with untreated diffuse large B-cell lymphoma (DLBCL). Tafasitamab is a humanized, monoclonal antibody designed to effectively target the B-cell specific antigen CD19 and to induce immune cell activation.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20210511006085/en/>

"While more than half of DLBCL patients can be cured with an aggressive chemotherapy regimen, current outcomes for high-risk patients are poor," said Mike Akimov, M.D., Ph.D., Head of Global Drug Development, MorphoSys. "We believe we may be able to make a difference for those DLBCL patients by adding the combination of tafasitamab and lenalidomide to R-CHOP, a current standard of care."

Each year, approximately 30,000 patients are diagnosed with DLBCL in the U.S. alone<sup>1,2</sup>. R-CHOP is a current standard of care for patients with previously untreated DLBCL, but about 40% of patients do not respond to R-CHOP or relapse – particularly those with high-intermediate and high-risk disease<sup>3</sup>.

"Despite improvements in treatment for patients with DLBCL, there continues to be a significant medical need for additional therapies with improved outcomes," said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapeutics, Incyte. "We are pleased to have initiated the *frontMIND* study as we seek meaningful, new options for newly diagnosed, high-risk patients with DLBCL."

In December 2020, encouraging preliminary data from *firstMIND*, the ongoing Phase 1b, open-label, randomized study on the safety and efficacy of R-CHOP plus either tafasitamab or tafasitamab plus lenalidomide for patients with newly diagnosed DLBCL, were [presented](#) at the American Society of Hematology (ASH) Annual Meeting. The data showed a preliminary response rate of 91.1% across both arms in a patient population that overall had a poor prognosis, and that the combination of tafasitamab, lenalidomide and R-CHOP has an acceptable tolerability profile. These results informed and supported further investigation of the tafasitamab combination in the *frontMIND* study.

In July 2020, the FDA approved Monjuvi® (tafasitamab-cxix) 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)<sup>4</sup>.

The FDA decision represented the first approval of a second-line treatment for adult patients with DLBCL who progressed during or after first-line therapy.

### About Diffuse Large B-cell Lymphoma (DLBCL)

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide<sup>5</sup>, characterized by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs. 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<sup>6</sup>.

### About frontMIND

The *frontMIND* (NCT04824092) trial is a randomized, double-blind, placebo-controlled, global Phase 3 clinical study in previously untreated high-intermediate and high-risk DLBCL patients that is conducted in partnership with the German Lymphoma Association (GLA), the Italian Lymphoma study group and the US Oncology Network.

The study aims to enroll approximately 880 DLBCL patients to receive either tafasitamab plus lenalidomide in addition to rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) or R-CHOP alone. The primary endpoint is investigator-assessed progression-free survival, according to Lugano 2014 criteria, and key secondary endpoints include event-free survival by investigator, overall survival, metabolic complete response rate by a Blinded Independent Review Committee, and overall response rate.

For more information about the *frontMIND* trial, visit <https://clinicaltrials.gov/ct2/show/study/NCT04824092?term=NCT04824092&draw=2&rank=1>.

### About Tafasitamab

Tafasitamab 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).

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 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 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 January 2020, MorphoSys and Incyte entered into a collaboration and licensing agreement to further develop and commercialize tafasitamab globally. Monjuvi® is being co-commercialized by Incyte and MorphoSys in the United States. Incyte has exclusive commercialization rights outside the United States.

A marketing authorization application (MAA) seeking the approval of tafasitamab in combination with lenalidomide in the EU has been validated by the European Medicines Agency (EMA) and is currently under review for the treatment of adult patients with relapsed or refractory DLBCL, including DLBCL arising from low grade lymphoma, who are not candidates for ASCT.

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

Monjuvi® is a registered trademark of MorphoSys AG.

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 chills, 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 Incyte**

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit [incyte.com](http://incyte.com) and follow [@incyte](https://twitter.com/incyte).

## About MorphoSys

MorphoSys (FSE & NASDAQ: MOR) is a commercial-stage biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for people living with cancer and autoimmune diseases. Based on its leading expertise in antibody, protein and peptide technologies, MorphoSys is advancing its own pipeline of new drug candidates and has created antibodies which are developed by partners in different areas of unmet medical need. In 2017, Tremfya® (guselkumab) – developed by Janssen Research & Development, LLC and marketed by Janssen Biotech, Inc., for the treatment of plaque psoriasis – became the first drug based on MorphoSys' antibody technology to receive regulatory approval. In July 2020, the U.S. Food and Drug Administration (FDA) granted accelerated approval of the company's proprietary product Monjuvi® (tafasitamab-cxix) in combination with lenalidomide in patients with a certain type of lymphoma. Headquartered near Munich, Germany, the MorphoSys group, including the fully owned U.S. subsidiary MorphoSys US Inc., has more than 600 employees. More information at [www.morphosys.com](http://www.morphosys.com) or [www.morphosys-us.com](http://www.morphosys-us.com).

Monjuvi® is a registered trademark of MorphoSys AG.

Tremfya® is a registered trademark of Janssen Biotech, Inc.

## Incyte Forward-looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the Company's ongoing clinical development program for tafasitamab, its *frontMIND* program, its diffuse large B-cell lymphoma (DLBCL) program generally and whether the combination of tafasitamab and lenalidomide with R-CHOP as first-line treatment will be approved for use in the U.S. or elsewhere for newly diagnosed patients with DLBCL, or any other indication, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the Company'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 and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers and development and discovery operations; determinations made by the U.S. FDA and other regulatory authorities; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2020 and the quarterly report on Form 10-Q for the quarter ended March 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

## 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

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- <sup>4</sup> Monjuvi® (tafasitamab-cxix) [Package Insert]. Boston, MA: MorphoSys; 2020.
- <sup>5</sup> 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](https://doi.org/10.1016/j.beha.2018.07.014).
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