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Incyte and MorphoSys Announce First Patient Dosed in Phase 3 inMIND Study Evaluating the Addition of Tafasitamab to Lenalidomide and Rituximab in Relapsed or Refractory Follicular or Marginal Zone Lymphoma

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WILMINGTON, Del. & PLANEGG, Germany & MUNICH--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) and MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ:MOR) today announced the first patient has been dosed in the placebo-controlled Phase 3 *inMIND* study evaluating the efficacy and safety of tafasitamab or placebo in combination with lenalidomide and rituximab in patients with relapsed or refractory follicular lymphoma (FL) or marginal zone lymphoma (MZL).

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20210419005587/en/>

"Despite improvements in treatment for patients with relapsed or refractory FL and MZL, 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 *inMIND* study as we seek meaningful, new options for patients with relapsed or refractory FL or MZL."

FL and MZL are the most common indolent, or slow growing, forms of B-Cell non-Hodgkin lymphomas (NHLs). FL and MZL account for approximately 20-25% and 7% of adult NHL cases, respectively.¹ There are limited treatment options for the more than 17,000 new cases of relapsed or refractory FL treated every year in the United States, Europe and Japan.²

"We are looking forward to building on previous, exploratory data in FL, and the results seen with tafasitamab and lenalidomide in relapsed or refractory diffuse large B-cell lymphoma, to evaluate the potential benefit of adding tafasitamab to the current lenalidomide and rituximab combination regimen in patients with indolent lymphomas," said Mike Akimov, M.D., Ph.D., Head of Global Drug Development, MorphoSys.

On January 7, 2021, the U.S. Food and Drug Administration granted orphan drug designation to tafasitamab for the treatment of FL.

About *inMIND*

inMIND (NCT04680052), a global, double-blind, placebo-controlled, randomized Phase 3 study, is evaluating whether tafasitamab and lenalidomide as an add-on to rituximab provides improved clinical benefit compared with lenalidomide alone as an add-on to rituximab 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 is expected to enroll over 600 adult (age ≥18 years) patients with relapsed or refractory FL or MZL.

The primary endpoint of the study is progression-free survival (PFS) in the FL population, and the key secondary endpoints are PFS and overall survival (OS) in the overall population as well as positron emission tomography complete response (PET-CR) at the end of treatment (EOT) in the FL population.

For more information about the study, please visit: <https://clinicaltrials.gov/ct2/show/NCT04680052>

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 and follow [@Incyte](#).

About MorphoSys

MorphoSys (FSE & NASDAQ: MOR) is a commercial-stage biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for patients suffering from cancer and autoimmune diseases. Based on its leading expertise in antibody, protein and peptide technologies, MorphoSys, together with its partners, has developed and contributed to the development of more than 100 product candidates, of which 27 are currently in clinical development. In 2017, Tremfya[®], 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 MorphoSys' 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 or 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 Incyte's ongoing clinical development program for tafasitamab in patients with relapsed/refractory follicular lymphoma (FL) or marginal zone lymphoma (MZL), the enrollment, design, and timing and results of the clinical trial program, including the *inMIND* study, and whether tafasitamab will become an approved treatment option for patients with relapsed or refractory FL or relapsed or refractory MZL, contain predictions, estimates and other forward-looking statements.

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 FDA; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of Incyte's products and the products of the Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte'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 Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2020. Incyte 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.

¹ Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revision of the World Health Organization classification of lymphoid neoplasms. *Blood* 2016;127:2375-2390.

² Decision Resources Group. Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia, Landscape & Forecast. 2020.



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