

MorphoSys and Incyte Announce Additional Real-World Evidence Results from RE-MIND2 Study of Tafasitamab (Monjuvi®) in Combination with Lenalidomide for the Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma

December 11, 2021

- *RE-MIND2 compared patient outcomes from pivotal L-MIND study with matched patient populations treated with NCCN/ESMO recommended therapies*
- *Results from the retrospective cohort analysis indicate significant overall survival improvement compared with Pola-BR and R2*

BOSTON & WILMINGTON, Del.--(BUSINESS WIRE)-- MorphoSys US Inc., a fully owned subsidiary of MorphoSys AG (FSE: MOR; NASDAQ: MOR), and Incyte (NASDAQ:INCY) today announced additional real-world evidence results from the RE-MIND2 study comparing tafasitamab (Monjuvi®) in combination with lenalidomide against the most frequently used treatments in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). These treatments include polatuzumab vedotin plus bendamustine and rituximab (Pola-BR), rituximab plus lenalidomide (R2), and CD19 chimeric antigen receptor T-cell (CAR-T) therapies. The data, which builds on the primary analysis [presented](#) at the 2021 Annual Meeting of the Society of Hematologic Oncology (SOHO 2021), will be presented as an oral presentation at the 63rd American Society of Hematology Annual Meeting and Exposition (ASH 2021), held December 11-14, 2021 in Atlanta, Georgia and virtually.

"In this retrospective cohort analysis, a statistically significant OS difference was observed, favoring tafasitamab plus lenalidomide over pola-BR and R2 in patients with relapsed or refractory DLBCL who are ineligible for transplant – a traditionally difficult-to-treat population," said Grzegorz Nowakowski, M.D., Professor of Medicine and Oncology at the Mayo Clinic, and lead investigator for the RE-MIND2 study*. "I am encouraged by the OS difference favoring tafasitamab plus lenalidomide and the comparable OS between tafasitamab and lenalidomide and CAR-T, specifically the potential prolonged survival benefit the tafasitamab plus lenalidomide combination may offer my patients."

Findings from the RE-MIND2 study presented at ASH 2021 indicated that tafasitamab plus lenalidomide resulted in statistically significant differences across several endpoints. Specifically, results showed:

- The primary endpoint, overall survival (OS), was met with significant improvement observed for tafasitamab plus lenalidomide at 20.1 months compared to Pola-BR at 7.2 months ($p=0.038$), and 24.6 months for tafasitamab plus lenalidomide compared to 7.4 months for R2 ($p=0.014$).
- A comparable median OS benefit was observed with tafasitamab plus lenalidomide at 22.5 months compared to CAR-T at 15 months without statistical significance.
- Objective response rate (ORR), a key secondary endpoint, was observed with statistical significance for tafasitamab plus lenalidomide at 63.6% versus R2 at 30.3% ($p=0.013$).
- Tafasitamab plus lenalidomide also achieved significantly higher complete response rate (CR), a key secondary endpoint, at 39.4% versus 15.2% for R2 ($p=0.0514$).
- While safety endpoints were not included in this study, the most common adverse events (AEs) associated with tafasitamab plus lenalidomide are feeling tired or weak, diarrhea, cough, fever, swelling of lower legs or hands, respiratory tract infection and decreased appetite.

Of 3,454 patients enrolled from 200 sites, 106, 106 and 149 patients were treated with pol-BR, R2 and CAR-T, respectively. For the comparative analysis, matched patient pairs were created using 1:1 nearest neighbor matching with a caliper. Matched pairs consisted of: tafasitamab + len vs pol-BR, $n=24$ pairs; vs R2, $n=33$; and vs CAR-T, $n=37$ pairs.

"The RE-MIND 2 Study is an example of our continued commitment to generating practice relevant real-world evidence which, in general, more realistically captures the clinical heterogeneity in cancer and allows us expanded opportunities to dynamically assess the patient experience. These data indicate that tafasitamab plus lenalidomide is a meaningful option for patients and has the potential to become a future backbone therapy in DLBCL," said Nuwan Kurukulasuriya, Ph.D., Senior Vice President, Global Head of Medical Affairs, MorphoSys.

"We are pleased to see the survival benefit for patients with relapsed or refractory DLBCL in the data from the RE-MIND2 study," said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapies, Incyte. "As we continue to establish tafasitamab in combination with lenalidomide as the standard of care in second-line treatment for DLBCL, we look forward to exploring the body of clinical evidence and bringing this novel treatment to patients with DLBCL and potentially even to other indications."

Presentations are available on the ASH website at <https://www.hematology.org/meetings/annual-meeting>; #183 (oral presentation).

In July 2020, the U.S. Food and Drug Administration (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 ASCT. This indication is approved under accelerated approval based on ORR. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The U.S. approval is based on an efficacy subgroup of 71 patients confirmed by central lab. 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 worldwide¹, 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 thereafter², leading to a high medical need for new, effective therapies³, especially for patients who are not eligible for an autologous stem cell transplant in this setting.

About RE-MIND2

The RE-MIND2 study is an observational, retrospective cohort study (NCT04697160) that compares outcomes with those from the L-MIND study for autologous stem cell transplant (ASCT)-ineligible patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), who are treated with therapies recommended by the National Comprehensive Cancer Network/European Society for Medical Oncology (NCCN/ESMO). The study utilized real-world data to generate external comparators for patients in the L-MIND trial. The primary analysis of the study compared patient outcomes from L-MIND with matched patient populations treated with gemcitabine-oxaliplatin plus rituximab (R-GemOx), bendamustine and rituximab (BR) and pooled systemic NCCN/ESMO recommended therapies. The additional analysis evaluated tafasitamab in combination with lenalidomide versus Pola-BR, R2 and CAR-T therapies. Patients enrolled in the study were aged 18 years or older with histologically confirmed DLBCL and had received two or more systemic therapies for DLBCL, including one or more anti-CD20 therapy. The study's primary endpoint is overall survival (OS). Secondary outcome measures include overall response rate (ORR), complete response rate (CRR), duration of response (DoR), event-free survival (EFS), progression-free survival (PFS), time to next treatment (TTNT), treatment discontinuation rate due to adverse events and duration of treatment exposure.

For more information about RE-MIND2, visit <https://clinicaltrials.gov/ct2/show/NCT04697160>.

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).

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

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[®] and Minjuvi[®] is a registered trademarks of MorphoSys AG.

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

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](https://twitter.com/incyte).

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.

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 expectations regarding the use of tafasitamab for treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), its ongoing clinical development program for tafasitamab, its L-MIND program, its diffuse large B-cell lymphoma (DLBCL) program generally and its further discussions with regulators regarding tafasitamab as a treatment for patients with DLBCL or for 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 FDA, European Medicines Agency (EMA), or 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; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended September 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

*Dr. Nowakowski has provided consulting and advisory services to MorphoSys.

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.

³ 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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