MorphoSys and Incyte Announce Five-Year Results of L-MIND Study Showed Prolonged, Durable Responses in Relapsed or Refractory DLBCL Patients Treated with Monjuvi® (tafasitamab-cxix)

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- Results from the Phase 2 L-MIND study were highlighted as a late-breaking oral presentation at the American Association for Cancer Research Annual Meeting 2023

BOSTON & WILMINGTON, Del.--(BUSINESS WIRE)--Apr. 16, 2023-- MorphoSys U.S. Inc., a fully owned subsidiary of MorphoSys AG (FSE: MOR; NASDAQ: MOR), and Incyte (Nasdaq: INCY) today announced final five-year follow-up data from the Phase 2 L-MIND study showing that Monjuvi® (tafasitamab-cxix) plus lenalidomide followed by Monjuvi monotherapy provided prolonged, durable responses in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). These data were featured as a late-breaking oral presentation (Abstract # CT022) at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando, Florida.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20230416005053/en/

“Five-year data demonstrating durability of response is meaningful for oncologists as they consider the most appropriate treatment option for a patient,” said Johannes Duell, M.D., University Hospital Würzburg Medical Clinic and Polyclinic. “The prolonged and durable responses seen at five years among relapsed or refractory DLBCL patients in the L-MIND study show that the Monjuvi treatment regimen may have curative potential, which I look forward to seeing explored in future studies.”

At the data cut-off (Nov. 14, 2022) for the full analysis set (80 patients), the overall response rate (ORR) was 57.5% (95% CI = 45.9, 68.5), and a complete response (CR) was observed in 41.2% of patients (95% CI = 30.4, 51.6; n = 33). A partial response (PR) was observed in 16.2% of patients (95% CI = 8.9, 26.2; n =13). Additional results include:

- Median duration of response was not reached after a median follow up of 44.0 months (95% CI = 29.9, 57.0).
- The median overall survival was 33.5 months (95% CI = 18.3, NR) and median progression-free survival was 11.6 months (95% CI = 5.7, 45.7).
- Of the 21 patients with >60 months of follow-up, 14 had received one prior line of therapy (pLoT), and seven patients had received ≥2 pLoT.
- Patients with one pLoT (n = 40) had a higher ORR of 67.5% (CR = 52.5% and PR = 15%) compared to 47.5% of patients with two or more pLoT (n = 40; CR = 30% and PR = 17.5%)

No new safety signals were identified. The majority of adverse events (AEs) were grade 1 or grade 2 during both combination and monotherapy treatment. Patients experienced a lower frequency of all-grade and grade 3 or higher adverse events during monotherapy. The most common adverse events with combination therapy were neutropenia (incidence per person per year, all-grade/grade ≥3: 3.79/2.09) and thrombocytopenia (1.52/0.52), which declined after patients switched to monotherapy (all-grade/grade ≥3: 1.09/0.70 and 0.17/0.06, respectively, in the first two years of monotherapy). Neutropenia and diarrhea were the most common adverse events in the first two years of monotherapy.

“The totality of the long-term L-MIND data presented at AACR further reinforce our confidence that the Monjuvi plus lenalidomide combination remains the in-practice, outpatient, targeted immunotherapy option that can provide sustained remissions for patients with relapsed or refractory DLBCL who are not eligible for autologous stem cell transplant,” said Tim Demuth, M.D., Ph.D., Chief Research and Development Officer, MorphoSys. “The durable responses and consistent safety profile observed in the five-year analysis are encouraging and further support the use of the Monjuvi regimen as a potentially curative option for appropriate patients.”

“The new five-year L-MIND data build on prior analyses that detail the potential for Monjuvi plus lenalidomide to provide long-term, meaningful responses for certain patients with relapsed or refractory DLBCL, a historically difficult-to-treat form of the disease,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We look forward to continuing to explore the potential of Monjuvi to help patients with newly diagnosed DLBCL, as well as other CD19-expressing lymphomas.”

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 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. Monjuvi, in combination with lenalidomide, was granted accelerated approval based on the one-year primary analysis of the L-MIND study. The data for the five-year analysis of the L-MIND study have not yet been submitted to, or reviewed by, the FDA.

About Diffuse Large B-cell Lymphoma (DLBCL)

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide[1], 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[2], leading to a high medical need for new, effective therapies[2], especially for patients who are not eligible for an autologous stem cell transplant in this setting.

About L-MIND

The L-MIND trial was a single arm, open-label Phase 2 study (NCT02399085) investigating the combination of tafasitamab and lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma who had at least one, but no more than three, prior lines of therapy, including an

anti-CD20 targeting therapy (e.g., rituximab), who were not eligible for high-dose chemotherapy or refused subsequent autologous stem cell transplant. The study's primary endpoint was overall response rate. Secondary outcome measures included duration of response, progression-free survival and overall survival. In May 2019, the study reached its primary completion. For more information about L-MIND, visit https://clinicaltrials.gov/ct2/show/NCT02399085.

About Monjuvi® (tafasitamab-cxix)
Tafasitamab is a humanized Fc-modified CD19 targeting 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 Europe and Canada.

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-related 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: *More life for people with cancer*. As a global commercial-stage biopharmaceutical company, we develop and deliver innovative medicines, aspiring to redefine how cancer is treated. 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.

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.

MorphoSys Forward-Looking Statements
This communication contains certain forward-looking statements concerning the MorphoSys group of companies. 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 that MorphoSys' expectations may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements, 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 contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: tafasitamab's ability to treat patients with relapsed or refractory diffuse large B-cell lymphoma, the further clinical development of tafasitamab, including ongoing confirmatory trials, additional interactions with regulatory authorities and expectations regarding future regulatory filings and possible additional approvals for tafasitamab as well as the commercial performance of tafasitamab. 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; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte and its partners' clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the U.S. FDA and other regulatory authorities outside of the United States; the efficacy or safety of Incyte and its partners' products; the acceptance of Incyte and its partners' products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

References

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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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