Data Evaluating Tafasitamab with and without Lenalidomide in Combination with R-CHOP in Patients with DLBCL Presented at ASH 2020

December 7, 2020

- Preliminary safety and efficacy data from Phase 1b firstMIND trial in patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL) presented today

- Also presented today: Long-term subgroup analyses from L-MIND study evaluating tafasitamab combined with lenalidomide in patients with relapsed or refractory DLBCL

WILMINGTON, Del. & PLANEGG/MUNICH, Germany--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) and MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ:MOR) announce that preliminary data from *firstMIND*, the ongoing Phase 1b, open-label, randomized study on the safety and efficacy of tafasitamab or tafasitamab plus lenalidomide in addition to R-CHOP for patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL) were presented today during the 62nd American Society of Hematology Annual Meeting & Exposition (ASH). Additionally, a long-term subgroup analysis of the L-MIND study investigating tafasitamab combined with lenalidomide in patients with relapsed or refractory DLBCL was also presented at ASH.

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The preliminary results of *firstMIND* indicate that tafasitamab plus lenalidomide in addition to R-CHOP shows an acceptable tolerability profile. Toxicities appear to be similar to what is expected with R-CHOP alone or in combination with lenalidomide. Serious or severe neutropenia and thrombocytopenia events (grade 3 or higher) were more frequent in the tafasitamab plus lenalidomide arm. The incidence of febrile neutropenia was comparable between both arms and the average relative dose intensity of R-CHOP was maintained in both arms. Interim response assessments after three cycles were available for 45 patients. In both arms combined, 41/45 (91.1%) of patients had an objective response as per Lugano 2014[1].

The preliminary data from this ongoing study in first-line DLBCL warrant further investigation. To that end, MorphoSys and Incyte plan to initiate *frontMIND*, a Phase 3 trial evaluating tafasitamab plus lenalidomide in combination with R-CHOP compared to R-CHOP alone as first-line treatment for patients with newly diagnosed DLBCL.

“The initial results of the *firstMIND* study, shared today at ASH, as well as the long-term analyses from L-MIND, underscore the potential of tafasitamab as a combination therapeutic for patients with DLBCL, where there remains a significant unmet need. Along with our partners at MorphoSys, we are pleased to be moving forward with the initiation of a Phase 3 study in 2021,” said Steven Stein, M.D., Chief Medical Officer at Incyte.

“The preliminary *firstMIND* study results mark another important step as we explore the potential of tafasitamab as a backbone therapy,” said Dr. Malte Peters, Chief Research and Development Officer at MorphoSys. “Given the data available to date, including data from the L-MIND study, we believe that the mechanism of action, efficacy and safety profile of tafasitamab have the potential to make it a preferred combination partner as we seek to transform the standard of care in DLBCL. We are committed to developing innovative therapies to battle this aggressive disease for the benefit of patients with DLBCL, and look forward to beginning the planned *frontMIND* in the first half of 2021.”

In addition to the *firstMIND* data presented today, the long-term L-MIND analyses showed that treatment with tafasitamab plus lenalidomide resulted in durable responses after ≥2 years of follow-up. At the time of analysis, patients with complete responses (CR) continued to experience durable treatment responses, including long duration of response (DoR) and overall survival (OS). The data also showed that tafasitamab plus lenalidomide taken for 12 cycles, followed by tafasitamab until progression, did not result in any unexpected safety signals[2].

In July 2020, the FDA approved Monjuvi® (tafasitamab-cxix), a humanized Fc-modified cytolytic CD19-targeting monoclonal antibody, 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)[3].

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[4], 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 one in three patients not responding to initial therapy or relapsing thereafter[5]. In the United States each year, approximately 10,000 patients are diagnosed with relapsed or refractory DLBCL who are not eligible for autologous stem cell transplant (ASCT)[6,7,8].

About *firstMIND*

The *firstMIND* (NCT04134936) trial is a Phase 1b, randomized study of tafasitamab + R-CHOP (Arm A) or tafasitamab + lenalidomide + R-CHOP (Arm B) in patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL). The study includes a safety run-in phase and a main phase. In the safety run-in phase, 24 patients were enrolled. The primary objective is to assess safety; secondary objectives include objective response rate, PET negative complete response (PET-CR) rate at end of treatment, progression-free survival, event-free survival, long-term safety, pharmacokinetics and immunogenicity of tafasitamab.

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.

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 exceptional, innovative therapies for patients suffering from serious diseases. The focus is on cancer. 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 ~500 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 about: plans to initiate frontMIND, a Phase 3 trial evaluating tafasitamab plus lenalidomide in combination with R-CHOP compared to R-CHOP alone as first-line treatment for patients with newly diagnosed DLBC; whether the mechanism of action, efficacy and safety profile of tafasitamab have the potential to make it a preferred or ideal combination partner in the treatment of DLBCL and, whether it will change or become the standard of care for the treatment of DLBCL; whether and when, if ever, confirmatory trials of tafasitamab will result in the conditional FDA approval of tafasitamab in the conditionally approved indication described above becoming a final approval; whether and when, if ever, the EMA will approve the filed MAA for tafasitamab; and additional development of tafasitamab, including in B-cell malignancies - contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the 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 or the EMA; clinical and commercial supply of products in development or being commercialized; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of Incyte's products and the products of its collaboration partners; the acceptance of Incyte's products and the products of its 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 quarterly report on Form 10-Q for the quarter ended September 30, 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.

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[1] Belada D, M.D., Ph.D., et al. A Phase 1b, Open-label, Randomized Study to Assess Safety and Preliminary Efficacy of Tafasitamab (MOR208) or Tafasitamab + Lenalidomide in Addition to R-CHOP in Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma: Analysis of the Safety Run-In Phase. 62nd American Society of Hematology Annual Meeting & Exposition (ASH). Abstract #3028.

[2] Maddocks KJ, M.D., et al. Long-Term Subgroup Analyses from L-MIND, a Phase 2 Study of Tafasitamab (MOR208) Combined with Lenalidomide in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma. 62nd American Society of Hematology Annual Meeting & Exposition (ASH). Abstract #3021.

[3] Monjuvi® (tafasitamab-cxix) Prescribing Information. Boston, MA, MorphoSys.

[4] 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.

[5] 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.

[6] DRG Epidemiology data.

[7] Kantar Market Research (TPP testing 2018).

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