FDA Approves Monjuvi® (tafasitamab-cxix) in Combination With Lenalidomide for the Treatment of Adult Patients With Relapsed or Refractory Diffuse Large B-cell Lymphoma (DLBCL)

July 31, 2020

- First FDA approval of a second-line treatment for adult patients with relapsed or refractory DLBCL, helping fill a high unmet medical need

- FDA granted Monjuvi Fast Track, Breakthrough Therapy and Priority Review designations

- MorphoSys and Incyte will co-commercialize Monjuvi in the United States

- Joint analyst and investor conference call and webcast scheduled for Monday, August 3, 2020 at 8:00 a.m. EDT / 2:00 p.m. CEST

PLANEGG, Germany & MUNICH & WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 31, 2020-- MorphoSys AG (FSE:MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ:MOR) and Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has approved Monjuvi® (tafasitamab-cxix) 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).[1] Monjuvi, a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody, has been approved under accelerated approval by the U.S. FDA based on overall response rate (ORR). Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The FDA decision represents the first approval of a second-line treatment for adult patients who progressed during or after first-line therapy.

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide[2], 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.[3] In the United States each year approximately 10,000 patients are diagnosed with relapsed or refractory DLBCL who are not eligible for ASCT.[4,5,6]

“We are incredibly proud that the FDA has approved Monjuvi in combination with lenalidomide as the first treatment in second-line for patients with relapsed or refractory DLBCL, and we thank all the health care professionals, patients and families involved in our Monjuvi trials,” said Jean-Paul Kress, M.D., Chief Executive Officer, MorphoSys. “This approval marks an important step in MorphoSys’ transformation into a fully integrated biopharmaceutical company. We remain committed to developing innovative treatments to improve the lives of patients with serious diseases.”

“The FDA approval of Monjuvi in combination with lenalidomide helps address an urgent unmet medical need for patients with relapsed or refractory DLBCL in the United States,” said Hervé Hoppenot, Chief Executive Officer, Incyte. “At Incyte we are committed to advancing patient care and are proud to bring this new and much-needed targeted therapeutic option to appropriate patients and the clinical community.”

“The FDA approval of Monjuvi brings a new treatment option to patients in dire need across the United States,” said Professor Gilles Salles, M.D., Chair of the Clinical Hematology Department at the University of Lyon, France, and lead investigator of the L-MIND study. “Today’s FDA decision offers new hope for patients with this aggressive form of DLBCL who progressed during or after first-line therapy.”

The FDA approval was based on data from the MorphoSys-sponsored Phase 2 L-MIND study, an open label, multicenter, single arm trial of Monjuvi in combination with lenalidomide as a treatment for adult patients with relapsed or refractory DLBCL. Results from the study showed an overall response rate (ORR) of 55% (primary endpoint), including a complete response (CR) rate of 37% and a partial response rate (PR) of 18%. The median duration of response (mDOR) was 21.7 months (key secondary endpoint).[1] Warnings and Precautions for Monjuvi included infusion-related reactions (6%), serious or severe myelosuppression (including neutropenia (50%), thrombocytopenia (18%), and anemia (7%)), infections (73%) and embryo-fetal toxicity. Neutropenia led to treatment discontinuation in 3.7% of patients. The most common adverse reactions (≥ 20%) were neutropenia, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral edema, respiratory tract infection, and decreased appetite.

The FDA previously granted Fast Track and Breakthrough Therapy Designation for the combination of Monjuvi and lenalidomide in relapsed or refractory DLBCL. FDA Breakthrough Therapy designation is intended to expedite development and review of drug candidates. It is granted if preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies in the treatment of a serious or life-threatening disease. The Biologics License Application (BLA) for Monjuvi was granted Priority Review and approved under the FDA’s Accelerated Approval program.

Monjuvi is expected to be commercially available in the United States shortly. MorphoSys and Incyte will co-commercialize Monjuvi in the United States. Incyte has exclusive commercialization rights outside the United States.

MorphoSys and Incyte are committed to supporting patients throughout their treatment journeys and are working together to help lower patient access barriers. As part of this commitment, the Companies have launched My Mission Support, a robust patient support program offering financial assistance, ongoing education and other resources to eligible patients who are prescribed Monjuvi in the United States. Program information will be available online at www.MyMissionSupport.com.

Conference Call Information
MorphoSys and Incyte will host an analyst and investor conference call and webcast on Monday, August 3, 2020 at 8:00 a.m. EDT / 2:00 p.m. CEST. The live webcast and replay will be available via www.morphosys.com and investor.incyte.com.

To access the conference call, please dial 877-407-3042 for callers in the United States or +1 201-389-0864 for callers outside the United States. When prompted, provide the conference identification number 13706810.

If you are unable to participate, a replay of the conference call will be available for 90 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is +1 201-612-7415. To access the replay, you will need the conference identification number 13706810.

About L-MIND
The L-MIND trial is 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 (DLBCL) who have had at least one, but no more than three prior lines of therapy, including an anti-CD20 targeting therapy (e.g., rituximab), who are not eligible for high-dose chemotherapy or refuse subsequent autologous stem cell transplant The study's primary endpoint is overall response rate (ORR). Secondary outcome measures include duration of response (DoR), progression-free survival (PFS) and overall survival (OS). 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)
Monjuvi 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 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).

In January 2020, MorphoSys and Incyte entered into a collaboration and licensing agreement to further develop and commercialize Monjuvi globally. Monjuvi will be 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 MorphoSys
MorphoSys 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, 27 of which are currently in clinical development. In 2017, Tremfya®, marketed by Janssen for the treatment of plaque psoriasis, became the first drug based on MorphoSys' antibody technology to receive regulatory approval. 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.

Tremfya® is a registered trademark of Janssen Biotech.

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, including the expectations 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. 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 as well as the commercial performance of tafasitamab, 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 subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: obtaining regulatory approval for this planned collaboration; research and development efforts related to the collaboration programs; the possibility that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; other market or economic factors, including other scientific developments; unanticipated delays; the effects of market competition; risks associated with relationships between collaboration partners; the impact of governmental actions regarding pricing, importation and reimbursement for pharmaceuticals; and such other risks detailed from time to time in each company's reports filed with the U.S. Securities and Exchange Commission, including Incyte's annual report on Form 10-Q for the quarter ending March 31, 2020 and MorphoSys' Annual Report on Form 20-F for the fiscal year ended December 31, 2019. Each party disclaims any intent or obligation to update these forward-looking

statements.

References

1. Monjuvi® (tafasitamab-cxix) Prescribing Information. Boston, MA, MorphoSys.
2. 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.
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.
4. DRG Epidemiology data.
5. Kantar Market Research (TPP testing 2018).
6. Friedberg, Jonathan W. Relapsed/Refractory Diffuse Large B-Cell Lymphoma. Hematology Am Soc Hematol Educ Program 2011; 2011:498-505. doi: 10.1182/asheducation-2011.1.498.

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MorphoSys
Media:
Jeanette Bressi
Director, US Communications
+1 617-404-7816
media@morphosys.com

Dr. Anca Ammon
Associate Director
+49 (0)89 899 27 26738
media@morphosys.com

Investors:
Dr. Anja Pomrehn
Senior Vice President
+49 (0)89 / 899 27 26972
anja.pomrehn@morphosys.com

Dr. Julia Neugebauer
Director
+49 (0)89 / 899 27 179
julia.neugebauer@morphosys.com

Incyte
Media:
Catalina Loveman
Executive Director, Public Affairs
+1 302 498 6171
cloveman@incyte.com

Jenifer Antonacci
Senior Director, U.S. Public Affairs
+1 302 498 7036
jantonacci@incyte.com

Investors:
Dr. Michael Booth
Division VP, IR & Global Responsibility
+1 302 498 5914
mbooth@incyte.com

Source: Incyte