National Comprehensive Cancer Network® Adds Monjuvi® (tafasitamab-cxix) to its Clinical Practice Guidelines in Oncology for B-cell Lymphomas

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PLANEGG, Germany & MUNICH & WILMINGTON, Del.--(BUSINESS WIRE)-- MorphoSys AG (FSE:MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ:MOR) and Incyte (Nasdaq:INCY) today announced that Monjuvi® (tafasitamab-cxix), a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody, has been included in the latest National Comprehensive Cancer Network® Clinical Practice Guidelines (NCCN Guidelines®) in Oncology for B-cell Lymphomas. Specifically, the NCCN Guidelines in the United States now include Monjuvi in combination with lenalidomide with a Category 2A designation as an option for the treatment of previously-treated adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma who are ineligible for autologous stem cell transplant (ASCT).

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“We are very gratified the NCCN acted quickly to include Monjuvi in combination with lenalidomide with a Category 2A designation in its Clinical Practice Guidelines in Oncology as a treatment for patients with relapsed or refractory DLBCL who are not candidates for transplant. This targeted therapeutic option helps address an immediate medical need for patients who previously had limited treatment options,” said Dr. Malte Peters, Chief Research & Development Officer, MorphoSys. “There is no other FDA-approved second line treatment for these patients with a 2A designation within the NCCN guidelines.”

The U.S. Food and Drug Administration (FDA) approved Monjuvi in combination with lenalidomide under accelerated approval on July 31, 2020, for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DBLCL arising from low grade lymphoma, and who are not eligible for ASCT. The approval was based on data from the MorphoSys-sponsored Phase 2 L-MIND study, an open label, multicenter single arm trial. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).[1]

The NCCN is a not-for-profit alliance of 30 leading cancer centers devoted to patient care, research and education. The intent of the NCCN Guidelines is to assist in the decision-making process of individuals involved in cancer care – including physicians, nurses, pharmacists, payers, patients and their families – with the ultimate goal of improving patient care and outcomes.

“The inclusion of Monjuvi in the NCCN Guidelines will help further inform healthcare providers of this advancement for patients,” said Peg Squier, M.D., Group Vice President, U.S. Medical Affairs, Incyte. “We believe Monjuvi has the potential to address an urgent medical need for patients with relapsed or refractory DLBCL and are pleased that the NCCN has acknowledged the clinical benefit of this targeted therapeutic option.”

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]

The updated NCCN Guidelines are available at www.nccn.org.

NCCN® and the NCCN Guidelines® are registered trademarks of National Comprehensive Cancer Network.

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-cxix 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 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 contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: Monjuvi’s potential to address an urgent medical need for patients with relapsed or refractory diffuse large B-cell lymphoma. 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: the efficacy and safety of Monjuvi; the acceptance of Monjuvi in the marketplace; determinations made by the FDA and regulatory agencies outside of the United States; the effects of market competition; and other risks detailed from time to time in Incyte’s reports filed with the U.S. Securities and Exchange Commission, including its quarterly report on Form 10-Q for the quarter ending June 30, 2020. Incyte disclaims any intent or obligation to update these forward-looking statements.

References:

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5. Kantar Market Research (TPP testing 2018).
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