MorphoSys and Incyte Announce the European Commission Approval of Minjuvi® (tafasitamab) in Combination with Lenalidomide for the Treatment of Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

-The decision by the European Commission is based on data from the L-MIND study evaluating tafasitamab in combination with lenalidomide as a treatment for patients with relapsed or refractory DLBCL
- Minjuvi is a new therapeutic option for eligible DLBCL patients in the European Union (EU), addressing an urgent unmet medical need
- In Europe, each year approximately 16,000 patients are diagnosed with relapsed or refractory DLBCL[1,2,3]

PLANEGG/MUNICH, Germany & WILMINGTON, Del., – August 26, 2021 – MorphoSys AG (FSE: MOR; NASDAQ: MOR) and Incyte (Nasdaq: INCY) today announced that the European Commission (EC) has granted conditional marketing authorization for Minjuvi® (tafasitamab) 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). The EC Decision follows the positive opinion received from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) in June 2021 recommending the conditional marketing authorization of Minjuvi.

"People living with relapsed or refractory DLBCL in the EU have historically had limited treatment options and a poor prognosis. However, with the EC's approval of Minjuvi, eligible patients now have a new and much needed treatment option," said Hervé Hoppenot, Chief Executive Officer, Incyte. "We will now focus our efforts on working with individual countries in Europe to provide people access to this new treatment."

"The approval of Minjuvi is a crucial milestone for patients with relapsed or refractory DLBCL in Europe," said Jean-Paul Kress, M.D., Chief Executive Officer, MorphoSys. "DLBCL is the most common type of non-Hodgkin lymphoma in adults and Minjuvi addresses an urgent unmet medical need for the 30-40% of people who do not respond to or relapse after initial therapy."

The conditional approval is based on the results from the L-MIND study evaluating the safety and efficacy of tafasitamab in combination with lenalidomide as a treatment for patients with relapsed or refractory DLBCL who are not eligible for autologous stem cell transplant (ASCT). The results showed best objective response rate (ORR) of 56.8% (primary endpoint), including a complete response (CR) rate of 39.5% and a partial response rate (PR) of 17.3%, as assessed by an independent review committee. The median duration of response (mDOR) was 43.9 months after a minimum follow up of 35 months (secondary endpoint). Tafasitamab together with lenalidomide was shown to provide a clinically meaningful response and the side effects were manageable. Warnings and precautions for tafasitamab include infusion-related reactions, myelosuppression, including neutropenia and thrombocytopenia, infections and tumour lysis syndrome.

“The data from the L-MIND study demonstrate the potential benefits, including long duration of response, that tafasitamab may have for eligible DLBCL patients,” said Professor Pier Luigi Zinzani M.D., Ph.D., Head of Lymphoma Group at University of Bologna. “It is encouraging to see new treatments become available for these patients, especially given the historical lack of treatment options in this area.”

Incyte and MorphoSys share global development rights to tafasitamab; Incyte has exclusive commercialization rights to tafasitamab outside the United States. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and is marketed by Incyte under the brand name Minjuvi® in the EU.

About Diffuse Large B-Cell Lymphoma
DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide, comprising 40% of all cases[4], and is characterized by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs[5]. It is an aggressive disease with about one in three patients not responding to initial therapy or relapsing thereafter[6]. In Europe, each year approximately 16,000 patients are diagnosed with relapsed or refractory DLBCL[7,8,9].

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 (HCD) or autologous stem cell transplant (ASCT). 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). The study reached its primary completion in May 2019.

For more information about L-MIND, visit https://clinicaltrials.gov/ct2/show/NCT02399085.

About Minjuvi® (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 approval, 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.

Safety Information from the EU Summary of Product Characteristics (SmPC)

Infusion-related reactions may occur and have been reported more frequently during the first infusion. Patients should be monitored closely throughout the infusion and should be advised to contact their healthcare professionals if they experience signs and symptoms of infusion related reactions including fever, chills, rash or breathing problems within 24 hours of infusion. A premedication should be administered to patients prior to starting tafasitamab infusion. Based on the severity of the infusion-related reaction, tafasitamab infusion should be interrupted or discontinued and appropriate medical management should be instituted.

Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with Minjuvi.

Minjuvi should be administered to patients with an active infection only if the infection is treated appropriately and well controlled. Patients with a history of recurring or chronic infections may be at increased risk of infection and should be monitored appropriately. Patients should be advised to contact their healthcare professionals if fever or other evidence of potential infection, such as chills, cough or pain on urination, develops.

Treatment with Minjuvi in combination with lenalidomide should not be initiated in female patients unless pregnancy has been excluded.

The most common adverse reactions were infections, neutropenia, asthenia, anemia, diarrhea, thrombocytopenia, cough, oedema peripheral, pyrexia and decreased appetite.

Minjuvi may cause serious adverse reactions. The most common serious adverse reactions were infection, including pneumonia and febrile neutropenia.

Treatment with tafasitamab can cause serious or severe myelosuppression including neutropenia, thrombocytopenia and anemia. Complete blood counts should be monitored throughout treatment and prior to administration of each treatment cycle.

About MorphoSys
MorphoSys (FSE & NASDAQ: MOR) is a commercial-stage biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for people living with cancer and autoimmune diseases. Based on its leading expertise in antibody and protein technologies, MorphoSys is advancing its own pipeline of new drug candidates and has created antibodies which are developed by partners in different areas of unmet medical need. In 2017, Tremfya® (guselkumab) – 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 the company's 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. subsidiaries MorphoSys US Inc. and Constellation Pharmaceuticals, Inc., has more than 750 employees. For more information visit www.morphosys.com or www.morphosys-us.com.

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.

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, including statements regarding the Company's expectations relating to the use of tafasitamab for treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), the Company's ongoing clinical development program for tafasitamab, and its DLBCL program generally, 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 European Commission and 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 June 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

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