Media Release

MorphoSys and Incyte Announce Positive CHMP Opinion for Tafasitamab in Combination with Lenalidomide for the Treatment of Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

- If approved, tafasitamab in combination with lenalidomide would represent an important new therapeutic option for eligible DLBCL patients in the European Union
- The positive opinion from the CHMP is based on data from the Phase 2 L-MIND study evaluating tafasitamab in combination with lenalidomide as a treatment for patients with relapsed or refractory DLBCL

PLANEGG/MUNICH, Germany and WILMINGTON, Del., USA – June 25, 2021 – MorphoSys AG (FSE: MOR; NASDAQ: MOR) and Incyte (NASDAQ: INCY) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending the conditional marketing authorization of tafasitamab in combination with lenalidomide, followed by tafasitamab 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 transplantation (ASCT).

"The CHMP's positive opinion of tafasitamab is a pivotal step towards addressing an urgent unmet medical need for the 30-40% of patients with relapsed or refractory DLBCL who do not respond to initial therapy or relapse thereafter," said Steven Stein, M.D., Chief Medical Officer, Incyte. "Following the U.S. FDA's approval of tafasitamab in July 2020, we eagerly await the European Commission's decision as we look forward to bringing this new therapy to eligible patients in Europe as soon as possible."

"Tafasitamab in combination with lenalidomide represents an important new targeted treatment option for patients with relapsed or refractory DLBCL," said Dr. Malte Peters, Chief Research & Development Officer, MorphoSys. "Patients with relapsed or refractory DLBCL have limited treatment options and often face a poor prognosis. There is an urgent need for effective therapies and if approved, this combination could provide patients in Europe with an important new therapeutic option."

The CHMP opinion to recommend the use of tafasitamab is now being reviewed by the European Commission, which has the authority to grant marketing authorization for medicinal products in the European Union (EU). If approved, tafasitamab would be commercialized in the EU under the brand name Minjuvi®.

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide comprising 40% of all cases[1] and characterized by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs.[2] It is an aggressive disease with about one in three patients not responding to initial therapy or relapsing thereafter.[3] In Europe, each year approximately 16,000 patients are diagnosed with relapsed or refractory DLBCL.[4,5,6]

MorphoSys and Incyte share global development rights to tafasitamab and Incyte has exclusive commercialization rights to tafasitamab outside the United States. MorphoSys and Incyte co-commercialize tafasitamab under the brand name Monjuvi® in the United States.

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 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 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).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

Minjuvi® and Monjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is marketed under the brand name Monjuvi® in the US. If approved in the EU, tafasitamab will be marketed under the brand name Minjuvi®.

XmAb® is a registered trademark of Xencor, Inc.

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. subsidiary MorphoSys US Inc., has more than 600 employees. More information at 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, including the expectations regarding Monjuvi's/Minjuvi'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 Monjuvi/Minjuvi. 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 Monjuvi/Minjuvi, 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 potential grant of marketing authorization for tafasitamab in the EU, the Company's expectations regarding 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; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2020 and the quarterly report on Form 10-Q for the quarter ended March 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

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