Health Canada Grants Marketing Authorization for Minjuvi® (tafasitamab) in Combination with Lenalidomide for the Treatment of Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Minjuvi is a new therapeutic option for eligible patients with DLBCL in Canada to address an urgent unmet medical need

PLANEGG/Munich, Germany, – August 24, 2021 – MorphoSys AG (FSE: MOR; NASDAQ: MOR) today announced that Health Canada has granted Incyte, its development and commercialization partner for tafasitamab, a Notice of Compliance with conditions for Minjuvi® (tafasitamab), a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody, 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, who are not eligible for autologous stem cell transplant (ASCT).

Incyte and MorphoSys share global development rights for 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 Canada.

“The approval of Minjuvi in Canada brings an innovative targeted immunotherapy to patients diagnosed with relapsed or refractory DLBCL, an area of significant unmet medical need, and we are confident in the ability of our partner Incyte to bring it to eligible patients who need it most. The documented safety profile and durable response shown in patients with relapsed or refractory DLBCL treated with tafasitamab plus lenalidomide, suggest the combination could potentially lead to durable remission," said Malte Peters, Chief Research and Development Officer at MorphoSys.

The conditional approval is based on data from the L-MIND study, an open label, multicenter single arm 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 ASCT, and is supported by the RE-MIND study, an observational retrospective study in relapsed or refractory DLBCL. Removal of the conditions from the Notice of Compliance is contingent upon verification and description of clinical benefit in a confirmatory trial(s). The results from L-MIND showed overall response rate (ORR) of 53.5% (primary endpoint), including a complete response (CR) rate of 35.2% and a partial response rate (PR) of 18.3%, as assessed by an independent review committee. The median duration of response (mDOR) was 34.6 months (secondary endpoint). Adverse events (AEs) reported included infusion-related

reactions, serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia, infections and tumour lysis syndrome.

About Diffuse Large B-cell Lymphoma (DLBCL)
DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide[1], 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 40% of patients not responding to initial therapy or relapsing thereafter[2], leading to a high medical need for new, effective therapies[3], especially for patients who are not eligible for an ASCT in this setting.

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 best objective 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 RE-MIND
RE-MIND, an observational retrospective study (NCT04150328), was designed to isolate the contribution of tafasitamab in combination with lenalidomide and to prove the combinatorial effect. The study compares real-world response data of patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who received lenalidomide monotherapy with the efficacy outcomes of the tafasitamab-lenalidomide combination, as investigated in MorphoSys' L-MIND trial. RE-MIND collected the efficacy data from 490 relapsed or refractory DLBCL patients in the U.S. and EU. Qualification criteria for matching patients of both studies were pre-specified. As a result, 76 eligible RE-MIND patients were identified and matched 1:1 to 76 of 80 L-MIND patients based on important baseline characteristics. Objective Response Rates (ORR) were validated based on this subset of 76 patients in RE-MIND and L-MIND, respectively. The primary endpoint of RE-MIND was met and shows a statistically significant superior best ORR of the tafasitamab-lenalidomide combination compared to lenalidomide monotherapy.
For more information about RE-MIND, visit https://clinicaltrials.gov/ct2/show/NCT04150328.

About Minjuvi® (tafasitamab)
Minjuvi® (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).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials. The safety and efficacy of tafasitimab in other B-cell malignancies has not been established.

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.

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.

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