Media Release
Planegg/Munich, Germany, December 12, 2021

MorphoSys presents latest data from the Phase 2 MANIFEST Study evaluating the potential of pelabresib in the treatment of myelofibrosis

- *Data presented during poster and oral sessions at the 63rd American Society of Hematology Annual Meeting and Exposition*
- *Latest results from the MANIFEST trial underscore the rationale to further explore pelabresib in combination with ruxolitinib in MANIFEST-2, a global, Phase 3, randomized, double-blind trial in treatment-naïve patients with myelofibrosis*

MorphoSys AG (FSE: MOR; NASDAQ: MOR) presented the latest data from the ongoing MANIFEST study, an open-label, Phase 2 clinical trial of pelabresib, an investigational BET inhibitor, in patients with myelofibrosis, a rare bone marrow cancer for which only limited treatment options are available. These latest results, which included more patients and longer-term follow-up than previously reported data, suggest the potential of pelabresib in the treatment of myelofibrosis. These findings were presented during poster and oral sessions at the 63rd American Society of Hematology Annual Meeting and Exposition (ASH 2021), held December 11 – 14, 2021 in Atlanta, Georgia and virtually.

“These data reconfirm previously published results and reinforce the role pelabresib may play, if approved, in overcoming some of the challenges we face in treating myelofibrosis,” said Malte Peters, M.D., MorphoSys Chief Research and Development Officer. “We are further exploring the effectiveness and safety of pelabresib as a first-line treatment for myelofibrosis in MANIFEST-2, an ongoing Phase 3 study. The latest results reaffirm our confidence in the MANIFEST-2 study, and we look forward to sharing findings from this trial once they become available.”

At ASH 2021, the latest data evaluating pelabresib as a first-line combination with ruxolitinib – the current standard of care – for patients with myelofibrosis who had not previously been treated with a JAK inhibitor (JAK inhibitor-naïve) were presented. As of September 10, 2021, the data cut-off, a total of 84 JAK inhibitor-naïve patients have been enrolled and received the combination. The data showed 68 percent (n=57) of patients treated with the combination achieved a ≥35 percent reduction in spleen volume (SVR35) from baseline at week 24 and 60 percent (n=47) maintained SVR35 at week 48. Most patients also saw their symptoms reduced, with 56 percent (n=46) achieving ≥50 percent reduction in total symptom score (TSS50) from baseline at week 24. At the time of the data cut-off, 53 patients (63 percent of the 84 patients) were still on treatment. No new safety signals were identified in the study. The most common hematologic adverse events were thrombocytopenia (12 percent, grade 3/4) and anemia (34 percent, grade 3/4). Non-hematological events included dyspnea (5 percent, grade 3) and respiratory tract infections (8 percent, grade 3/4).

Additionally, analyses from an exploratory endpoint presented at ASH 2021 showed a reduction of megakaryocyte clustering in bone marrow and correlation with spleen volume reduction. Megakaryocytes are the cells in the bone marrow responsible for making platelets, and the clustering of these cells are one of the signs of myelofibrosis. The exploratory data,

which require further evaluation, suggest the potential pelabresib may have in changing the course of myelofibrosis treatment, if approved.

“In my opinion, a challenge in treating myelofibrosis is knowing that despite available treatment options the disease will ultimately progress in the majority of patients diagnosed,” said Srdan Verstovsek, M.D., Ph.D., professor of medicine and hematologist-oncologist at the MD Anderson Cancer Center and a MANIFEST investigator. “Identifying new, first-line treatment options will improve physicians’ ability to better manage the disease from the time of diagnosis. These latest data, although early in the investigational process, suggest that by combining pelabresib and ruxolitinib, we may have the potential to enhance the current standard of care in the first-line treatment of myelofibrosis.”

Additional data from Arm 1 of the MANIFEST study were also presented in an oral presentation at ASH 2021. In Arm 1, pelabresib is being evaluated as a monotherapy in patients with advanced myelofibrosis who are ineligible to receive, intolerant of, or refractory to JAK inhibitors, a population with very limited therapeutic options. Patients were divided into two cohorts, transfusion-dependent (TD) and non-transfusion-dependent (non-TD). For the TD cohort, the primary endpoint was conversion to transfusion independence (TI) for 12 consecutive weeks. In the non-TD cohort, the primary endpoint was SVR35 at week 24. At week 24, 11 percent (n=7) of patients reached SVR35. In addition, we observed 31 percent of patients had a spleen volume reduction of 25 percent or more (n=20) at week 24. Across all cohorts, 28 percent (n=18) of patients achieved TSS50. No new safety signals were identified in the study. The most common hematologic adverse events were thrombocytopenia (23 percent, grade 3/4) and anemia (15 percent, grade 3). Non-hematological events included diarrhea (6 percent, grade 3) and respiratory tract infections (5 percent, grade 3).

About Pelabresib
Pelabresib (CPI-0610) is an investigational selective small-molecule designed to promote anti-tumor activity by inhibiting the function of bromodomain and extra-terminal domain (BET) proteins to decrease the expression of abnormally expressed genes in cancer. Pelabresib is currently being investigated as a treatment for myelofibrosis and has not yet been evaluated or approved by any regulatory authorities.

About MANIFEST
MANIFEST is an open-label, Phase 2 clinical trial of pelabresib (CPI-0610) in patients with myelofibrosis (MF), a rare cancer of the bone marrow that disrupts the body’s normal production of blood cells.

Constellation Pharmaceuticals, an affiliate of MorphoSys, is evaluating pelabresib in combination with ruxolitinib in JAK-inhibitor-naïve MF patients (Arm 3), with a primary endpoint of the proportion of patients with a ≥35% spleen volume reduction from baseline (SVR35) after 24 weeks of treatment. Constellation Pharmaceuticals is also evaluating pelabresib either as a monotherapy in patients who are resistant to, intolerant of, or ineligible for ruxolitinib and no longer on the drug (Arm 1) or as add-on therapy in combination with ruxolitinib in patients with a suboptimal response to ruxolitinib or MF progression (Arm 2). Patients in Arms 1 and 2 are being stratified based on transfusion-dependent (TD) status. The primary endpoint for the patients in cohorts 1A and 2A, who were TD at baseline, is conversion to transfusion independence for 12 consecutive weeks. The primary endpoint for patients in cohorts 1B and 2B, who were not TD at baseline, is the proportion of patients with a ≥35% spleen volume reduction from baseline after 24 weeks of treatment.

About MorphoSys
MorphoSys (FSE & NASDAQ: MOR) is a 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 that 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 granted accelerated approval of the company's proprietary product Monjuvi® (tafasitamab-cxix) in combination with lenalidomide for 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.

Monjuvi® is a registered trademark of MorphoSys AG.

Tremfya® is a registered trademark of Janssen Biotech, Inc.

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