Media Release
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MorphoSys Presents Multiple Analyses of the MANIFEST Phase 2 Trial Investigating the Potential of Pelabresib in the Treatment of Myelofibrosis at EHA 2022

New translational data suggests potential disease-modifying effects following treatment with pelabresib of both first-line and ruxolitinib-relapsed/refractory patients

A comparative model suggests an improvement in SVR35 and TSS50 in JAK inhibitor-naïve myelofibrosis patients treated with pelabresib plus ruxolitinib over JAK inhibitors as monotherapy

Additional presentations include positive interim data from the MANIFEST Phase 2 trial and design of MANIFEST-2, a global Phase 3, randomized, double-blind trial of pelabresib in combination with ruxolitinib in treatment-naïve patients

MorphoSys AG (FSE: MOR; NASDAQ: MOR) is presenting data from multiple analyses of 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. The latest findings suggest pelabresib may have disease-modifying properties and confirm previous data supporting the potential of pelabresib as a treatment for patients with myelofibrosis. The data are being presented during oral and poster sessions at the European Hematology Association 2022 (EHA 2022) Hybrid Congress being held in Vienna.

“The standard for evaluating disease response in myelofibrosis focuses on symptom relief rather than true disease modification, which remains an unmet need for these patients,” said John Mascarenhas, M.D., Director of the Adult Leukemia Program at The Tisch Cancer Institute at Mount Sinai, New York. “The body of data being presented at EHA 2022 – including new findings that pelabresib may address cellular defects seen in myelofibrosis, thereby getting at the root cause of the disease – with correlated clinical improvements, suggests pelabresib may have the potential to enhance the current standard of care in the first-line treatment of myelofibrosis.”

A study that will be presented in an oral session on June 11 analyzed cells derived from blood of patients who enrolled in the MANIFEST trial and from healthy volunteers. The findings indicate that pelabresib alone or in combination with the JAK inhibitor ruxolitinib may have the potential to improve the typical imbalance in the two white blood cell populations, the myeloid and lymphoid cells, and help restore normal blood cell development. These improvements also correlated with decreases in spleen volume, a key clinical measure of treatment success. Additionally, pelabresib alone or in combination decreased pro-inflammatory and pro-fibrotic signaling in monocytes, suggesting a potential attenuation of disease processes.

“The latest findings from the MANIFEST trial at EHA 2022 highlight the potential of pelabresib to offer patients and their physicians benefits over monotherapy with JAK inhibitors, if approved,” said Malte Peters, M.D., MorphoSys Chief Research and Development Officer. “The full complement of MANIFEST data being presented this week suggests pelabresib may

help improve outcomes for patients with myelofibrosis and reaffirms our confidence in the Phase 3 MANIFEST-2 study. We are committed to these patients, who need better options in first-line treatment and beyond."

A second oral presentation on June 11 highlights positive interim data from the MANIFEST trial on the safety and efficacy of pelabresib in combination with ruxolitinib in patients who were not previously treated with a JAK inhibitor and in those with suboptimal response to ruxolitinib. The findings show that the combination was generally well tolerated and offered reductions in spleen volume and symptom burden, with disease-modifying activity as measured by reduced levels of pro-inflammatory cytokines and improved bone marrow morphology. Over two-thirds (68%; n=57) of JAK inhibitor-naïve patients treated with the combination achieved at least a 35% reduction in spleen volume (SVR35) from baseline at week 24. Notably, 80% of patients achieved SVR35 at any time on study. Most patients also saw their symptoms reduced, with 56% (n=46) achieving at least a 50% reduction in total symptom score (TSS50) from baseline at week 24. No new safety signals were identified in the study. The most common hematologic adverse events were thrombocytopenia (12%, grade 3/4) and anemia (34%, grade 3/4). Non-hematological events included dyspnea (5%, grade 3) and respiratory tract infections (8%, grade 3/4).

In a poster presentation at EHA 2022, matching-adjusted indirect comparisons were used to compare findings for the combination of pelabresib plus ruxolitinib in treatment-naïve patients with intermediate- or high-risk disease in one arm of the MANIFEST trial with findings from historical clinical trials examining the use of JAK inhibitor monotherapy in myelofibrosis. Adjusting for cross-trial differences, the estimated response rate ratios favored the pelabresib combination over ruxolitinib, fedratinib or momelotinib monotherapy for SVR35 and for TSS50, suggesting improved efficacy versus the JAK inhibitors alone.

A second poster presentation includes trial design information for the Phase 3 MANIFEST-2 study. MANIFEST-2, which is currently enrolling, will compare pelabresib in combination with ruxolitinib versus placebo plus ruxolitinib in approximately 400 patients with myelofibrosis who are naïve to JAK inhibitor therapy. MorphoSys is expected to report topline data from the MANIFEST-2 trial in the first half of 2024.

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 being investigated as a treatment for myelofibrosis and has not yet been evaluated or approved by any regulatory authorities.

About Myelofibrosis
Myelofibrosis is a type of chronic leukemia that causes extensive scarring in the bone marrow, which disrupts the body's normal production of healthy blood cells. The result is a reduction in red blood cells, which can cause weakness and fatigue, and in platelets, which increases the risk of bleeding due to deficient clotting. Myelofibrosis often causes an enlarged spleen. It is most often diagnosed in people older than 50 and can occur on its own (called primary myelofibrosis) or because of another bone marrow disorder.

About MANIFEST
MANIFEST (NCT02158858) is an open-label Phase 2 clinical trial of pelabresib in patients with myelofibrosis.

The MANIFEST trial is evaluating pelabresib in combination with ruxolitinib in JAK-inhibitor-naïve myelofibrosis 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. The trial 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 myelofibrosis 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.

Constellation Pharmaceuticals, Inc., a MorphoSys company, is the MANIFEST trial sponsor.

About MANIFEST-2
MANIFEST-2 (NCT04603495) is a global, double-blind, randomized Phase 3 clinical trial with pelabresib in combination with ruxolitinib versus placebo plus ruxolitinib in JAK inhibitor-naïve patients with myelofibrosis. The primary endpoint of the study is a 35% or greater reduction in spleen volume (SVR35) from baseline at 24 weeks. A key secondary endpoint of the study is a 50% or greater improvement in total symptom score (TSS50) from baseline at 24 weeks.

Constellation Pharmaceuticals, Inc., a MorphoSys company, is the MANIFEST-2 trial sponsor.

About MorphoSys:
At MorphoSys, we are driven by our mission: *More life for people with cancer*. As a global commercial-stage biopharmaceutical company, we use groundbreaking science and technologies to discover, develop, and deliver innovative cancer medicines to patients. MorphoSys is headquartered in Planegg, Germany, and has its U.S. operations anchored in Boston, Massachusetts. To learn more, visit us at www.morphosys.com and follow us on Twitter and LinkedIn.

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