



Media Release

Planegg/Munich, Germany, May 11, 2023

MorphoSys Highlights Potential of Its Mid- to Late-Stage Oncology Pipeline at 2023 ASCO and EHA Annual Meetings

MorphoSys AG (FSE: MOR; NASDAQ: MOR) today announced that the latest data on multiple pipeline therapies will be presented during the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois from June 2 to 6, 2023 and at the European Hematology Association (EHA) Hybrid Congress in Frankfurt, Germany from June 8 to 11, 2023. Presentations will include data on pelabresib, an investigational BET inhibitor; tafasitamab, a CD19-targeting immunotherapy, marketed in the U.S. in partnership with Incyte as Monjuvi[®] and outside the U.S. by Incyte as Minjuvi[®]; and tulmimetostat, an investigational next-generation dual inhibitor of EZH2 and EZH1.

“With pelabresib, we have the near-term potential to improve the standard of care for patients with myelofibrosis and the opportunity to expand into other myeloid diseases where new treatment options are still needed,” said Tim Demuth, M.D., Ph.D., MorphoSys Chief Research and Development Officer. “The data we are presenting at ASCO and EHA showcase the breadth and depth of our mid- to late-stage pipeline. We are committed to addressing the critical needs of patients with blood cancers, including myeloid malignancies, and those with solid tumors.”

Pelabresib is being investigated in the Phase 2 MANIFEST study in patients with myelofibrosis and essential thrombocythemia and in the Phase 3 MANIFEST-2 study in combination with ruxolitinib as a first-line treatment for myelofibrosis. Myelofibrosis and essential thrombocythemia are both myeloproliferative neoplasms, which are types of blood cancers that begin with a genetic change in bone marrow stem cells. The presentations on pelabresib include:

- An oral presentation at EHA and a poster discussion at ASCO on new preliminary results from MANIFEST Arm 4 exploring pelabresib as a monotherapy in patients with high-risk essential thrombocythemia who are refractory or intolerant to hydroxyurea, the chemotherapeutic agent most used to treat the disease.
- A poster presentation at EHA showcasing clinical data from MANIFEST Arm 3 evaluating pelabresib in combination with ruxolitinib for the treatment of patients with myelofibrosis who had not previously been treated with a JAK inhibitor ([previously presented](#) at American Society of Hematology [ASH 2022] Annual Meeting and Exposition).
- A poster presentation at EHA with clinical data from MANIFEST Arm 2 evaluating pelabresib as add-on therapy to ruxolitinib in myelofibrosis patients with a suboptimal response or disease progression following treatment with ruxolitinib (previously presented at ASH 2022).

Monjuvi in combination with lenalidomide was investigated in the Phase 2 L-MIND study in patients with relapsed or refractory diffuse large B-cell lymphoma. The presentations on Monjuvi include:

- A poster presentation at EHA of final five-year efficacy and safety data from L-MIND ([previously presented](#) at American Association for Cancer Research Annual Meeting 2023).
- An e-publication at ASCO and EHA of a new five-year sub-group analysis from L-MIND.

Tulmimetostat is being evaluated in a Phase 1/2 trial in patients with advanced solid tumors or lymphomas, including *ARID1A*-mutated ovarian clear cell carcinoma and endometrial carcinoma, *BAP1*-mutated mesothelioma, and peripheral T-cell lymphoma. Tulmimetostat was designed to improve on first-generation EZH2 inhibitors through increased potency, longer residence time on target and a longer half-life, offering the potential for enhanced anti-tumor activity.

- At ASCO, preliminary results from the Phase 2 portion of the study evaluating tulmimetostat across multiple tumor types will be presented during a poster session.

ASCO Abstract Titles	Session Type	Abstract Number	Presentation Date/Time
Pelabresib (CPI-0610) Monotherapy in High-Risk Essential Thrombocythemia Refractory or Intolerant to Hydroxyurea: Preliminary Results From MANIFEST Study	Poster Discussion	7019	June 5, 12:30 PM – 2:00 PM ET / 6:30 PM – 8:00 PM CEST
EZH2/EZH1 Inhibitor Tulmimetostat (CPI-0209) in Patients with Advanced Solid Tumors or Hematologic Malignancies: Preliminary Phase 2 Results	Poster	3094	June 3, 9:00 AM – 10:00 AM ET / 3:00 PM – 5:00 PM CEST
Five-year Subgroup Analysis of Tafasitamab + Lenalidomide from the Phase II L-MIND Study in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma	E-Publication	E19522	N/A

EHA Abstract Titles	Session Type	Abstract Number	Presentation Date/Time
Pelabresib (CPI-0610) Monotherapy in Patients With High-Risk Essential Thrombocythemia Refractory or Intolerant to Hydroxyurea: Preliminary Results From MANIFEST Study	Oral	S168	June 9, 9:30 AM – 9:45 AM ET / 3:30 PM – 3:45 PM CEST
Updated Durability of Response and Safety in MANIFEST Arm 3: Pelabresib (CPI-0610) Combined With Ruxolitinib for JAK Inhibitor Treatment-Naïve Patients With Myelofibrosis	Poster	P1027	June 9, 12:00 PM – 1:00 PM ET / 6:00 PM – 7:00 PM CEST
Updated Results From MANIFEST Arm 2: Efficacy and Safety of	Poster	P1018	June 9, 12:00 PM – 1:00 PM ET / 6:00 PM – 7:00 PM CEST

Pelabresib (CPI-0610) as Add-on to Ruxolitinib in Myelofibrosis

Five-year Efficacy and Safety of Tafasitamab in Patients with Relapsed or Refractory DLBCL: Final Results from the Phase II L-MIND Study Poster P1138 June 9, 12:00 PM – 1:00 PM ET / 6:00 PM – 7:00 PM CEST

Five-year Subgroup Analysis of Tafasitamab + Lenalidomide from the Phase II L-MIND Study in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma E-Publication PB2304 N/A

Please refer to the [ASCO 2023 online program](#) and [EHA 2023 online program](#) for full session details and data presentation listings.

About MorphoSys

At MorphoSys, we are driven by our mission: *More life for people with cancer*. As a global commercial-stage biopharmaceutical company, we develop and deliver innovative medicines, aspiring to redefine how cancer is treated. 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](#).

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 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 $\geq 35\%$ 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 $\geq 35\%$ spleen volume reduction from baseline after 24 weeks of treatment. The study is also evaluating pelabresib as a monotherapy in patients with high-risk essential thrombocythemia who are intolerant of, or refractory to, hydroxyurea (Arm 4). The primary endpoint for patients in Arm 4 is complete hematological response rate after one cycle, or 21 days, 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. The 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 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 marketing authorization 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.

Monjuvi® and Minjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in the EU.

XmAb® is a registered trademark of Xencor, Inc.

Important Safety Information

What are the possible side effects of MONJUVI?

MONJUVI may cause serious side effects, including:

- Infusion reactions. Your healthcare provider will monitor you for infusion reactions during your infusion of MONJUVI. Tell your healthcare provider right away if you get fever, chills, rash, flushing, headache, or shortness of breath during an infusion of MONJUVI.
- Low blood cell counts (platelets, red blood cells, and white blood cells). Low blood cell counts are common with MONJUVI, but can also be serious or severe. Your healthcare provider will monitor your blood counts during treatment with MONJUVI. Tell your healthcare provider right away if you get a fever of 100.4°F (38°C) or above, or any bruising or bleeding.
- Infections. Serious infections, including infections that can cause death, have happened in people during treatments with MONJUVI and after the last dose. Tell your healthcare provider right away if you get a fever of 100.4°F (38°C) or above, or develop any signs and symptoms of an infection.

The most common side effects of MONJUVI include:

- Feeling tired or weak
- Diarrhea
- Cough
- Fever
- Swelling of lower legs or hands
- Respiratory tract infection
- Decreased appetite

These are not all the possible side effects of MONJUVI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before you receive MONJUVI, tell your healthcare provider about all your medical conditions, including if you:

- Have an active infection or have had one recently.
- Are pregnant or plan to become pregnant. MONJUVI may harm your unborn baby. You should not become pregnant during treatment with MONJUVI. Do not receive treatment with MONJUVI in combination with lenalidomide if you are pregnant because lenalidomide can cause birth defects and death of your unborn baby.
 - You should use an effective method of birth control (contraception) during treatment and for at least 3 months after your final dose of MONJUVI.
 - Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with MONJUVI.
- Are breastfeeding or plan to breastfeed. It is not known if MONJUVI passes into your breastmilk. Do not breastfeed during treatment for at least 3 months after your last dose of MONJUVI.

You should also read the lenalidomide Medication Guide for important information about pregnancy, contraception, and blood and sperm donation.

Tell your healthcare provider about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see the full [Prescribing Information](#) for Monjuvi, including Patient Information, for additional Important Safety Information.

About L-MIND

The L-MIND trial was 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 who had at least one, but no more than three, prior lines of therapy, including an anti-CD20 targeting therapy (e.g., rituximab), who were not eligible for high-dose chemotherapy or refused subsequent autologous stem cell transplant. The study's primary endpoint was overall response rate. Secondary outcome measures included duration of response, progression-free survival and overall survival. In May 2019, the study reached its primary completion.

About Tulumimmetostat

Tulumimmetostat (CPI-0209) is an investigational compound designed to exert anti-tumor activity by inhibiting the function of enhancer of zeste homolog 1 and 2 (EZH2 and EZH1) proteins to reactivate silenced genes like tumor suppressor genes. Tulumimmetostat is being tested as a once-daily oral treatment in a [Phase 1/2 trial \(NCT04104776\)](#) in patients with advanced solid tumors or lymphomas, including *ARID1A*-mutated ovarian clear cell carcinoma and endometrial carcinoma, diffuse large B-cell lymphoma, peripheral T-cell lymphoma, *BAP1*-mutated mesothelioma and castration-resistant prostate cancer. The primary outcome measures include frequency of dose-limiting toxicities, maximum tolerate dose and overall response rate.

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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