



Media Release
BOSTON, Mass., USA, November 3, 2022

MorphoSys to Share New Data on Pelabresib and Monjuvi® (tafasitamab-cxix) in 14 Presentations at the American Society of Hematology Annual Meeting

Presentations – including four oral sessions – feature data supporting the potential benefit of first-line therapy for pelabresib in myelofibrosis and tafasitamab in diffuse large B-cell lymphoma

Data add to the growing confidence in MorphoSys' pipeline and its pivotal trials

MorphoSys U.S. Inc., a fully owned subsidiary of MorphoSys AG (FSE: MOR; NASDAQ: MOR), today announced that new data on pelabresib, an investigational BET inhibitor, and tafasitamab, marketed in the U.S. as Monjuvi® and outside the U.S. by Incyte as Minjuvi®, will be featured in 14 presentations – including four oral sessions – during the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in New Orleans, Louisiana from December 10-13, 2022.

“The comprehensive set of data we’re presenting at ASH reaffirms our confidence in our ongoing pivotal studies, including MANIFEST-2 and *frontMIND*, that are evaluating whether these investigational therapies can enhance the standard of care for patients with difficult-to-treat blood cancers,” said Tim Demuth, M.D., Ph.D., MorphoSys Chief Research and Development Officer. “We are committed to helping patients who need better options for first-line treatment and beyond. These latest presentations showcase the quality of science and potential solutions coming out of our research and development efforts.”

Key data being presented at ASH 2022 will include:

- An oral presentation on results from the ongoing Phase 2 MANIFEST study evaluating clinical benefit and biomarker changes, indicating potential disease modification following treatment with pelabresib as monotherapy or in combination with ruxolitinib in patients with myelofibrosis.
- An oral presentation from the ongoing Phase 2 MANIFEST study highlighting durability of response and safety beyond 24 weeks for pelabresib in combination with ruxolitinib in JAK inhibitor-naïve patients with myelofibrosis.
- An oral presentation and a poster presentation on minimal residual disease (MRD)-negativity to serve as a potential surrogate endpoint and predictor of outcomes after front-line therapy with tafasitamab plus lenalidomide and R-CHOP in diffuse large B-cell lymphoma (DLBCL).
- A poster presentation of final, 18-month data from the *firstMIND* study to assess the safety of tafasitamab or tafasitamab plus lenalidomide and R-CHOP in patients with newly diagnosed DLBCL, including data on overall response rates, duration of response and progression-free survival rates in MRD-negative patients.
- A poster presentation of an additional data analysis from the L-MIND study that offers further insight into the safety and long-term use of tafasitamab in patients with relapsed or refractory DLBCL, including data on the duration of response in patients who have

undergone treatment for at least two years, some of whom have been treated for five years or more.

ASH 2022 Accepted Abstracts

Abstracts listed below include both MorphoSys-led and partner abstracts.

Abstract Title	Abstract Number	Date/Time
Pelabresib		
ORAL Pelabresib (CPI-0610) Combined With Ruxolitinib for JAK Inhibitor Treatment-Naïve Patients With Myelofibrosis: Durability of Response and Safety Beyond Week 24	#238	Saturday, December 10, 2022 2:45 p.m. CST / 9:45 p.m. CET
ORAL Clinical Benefit Associated With Biomarker Changes Indicative of Disease Modification in Patients With Myelofibrosis Treated With the BET Inhibitor Pelabresib as Monotherapy or in Combination With Ruxolitinib	#630	Sunday, December 11, 2022 5:45 p.m. CST / 12:45 a.m. CET on December 12, 2022
POSTER Pelabresib (CPI-0610) as Add-on to Ruxolitinib in Myelofibrosis: Durability of Response and Safety Beyond Week 24 in the Phase 2 MANIFEST Study	#4344	Monday, December 12, 2022 6:00 p.m. CST / 1:00 a.m. CET on December 13, 2022
PUBLICATION Improvement in Individual Symptoms and Total Symptom Score (TSS) and Matching-Adjusted Indirect Comparison (MAIC) Analysis to Compare TSS as a Continuous Endpoint in Patients With Myelofibrosis Treated With Pelabresib in Combination With Ruxolitinib Versus Janus Kinase Inhibitor Monotherapy	N/A	N/A
Tafasitamab		
ORAL MRD-negativity as a potential surrogate endpoint after frontline DLBCL therapy: pooled analysis & implications for clinical trial design	#322	Saturday, December 10, 2022 4:45 p.m. CST / 11:45 p.m. CET
ORAL CD19 antigen occupancy on cancer cells with the CD19 monoclonal antibody tafasitamab improves the activation, antitumor efficacy, and safety profile of CART19 cell therapy	#977	Monday, December 12, 2022 5:30 p.m. CST / 12:30 a.m. CET on December 13, 2022

<p>POSTER <i>first</i>MIND: Final Analysis from a Phase Ib, Open-Label, Randomized Study to Assess Safety of Tafasitamab or Tafasitamab + Lenalidomide in Addition to RCHOP in Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma</p>	#1619	Saturday, December 10, 2022 5:30 p.m. CST / 12:30 a.m. CET on December 11, 2022
<p>POSTER <i>front</i>MIND: A Phase III, Multicenter, Randomized, Double-Blind Study of Tafasitamab + Lenalidomide + R-CHOP versus R-CHOP Alone for Newly Diagnosed High-Intermediate and High-Risk Diffuse Large B-Cell Lymphoma</p>	#2947	Sunday, December 11, 2022 6:00 p.m. CST / 1:00 a.m. CET on December 12, 2022
<p>POSTER L-MIND: A Safety and Efficacy Analysis of Tafasitamab in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) Receiving Treatment for at Least 2 Years</p>	#2937	Sunday, December 11, 2022 6:00 p.m. CST / 1:00 a.m. CET on December 12, 2022
<p>POSTER Relationship of Ultrasensitive ctDNA MRD & Outcomes in DLBCL after Frontline Therapy with Tafasitamab in Combination with Lenalidomide & R-CHOP</p>	#1519	Saturday, December 10, 2022 5:30 p.m. CST / 12:30 a.m. CET on December 11, 2022
<p>POSTER Blocking the CD47-SIRPa Axis enhances Tafasitamab-mediated phagocytosis</p>	#4185	Monday, December 12, 2022 6:00 p.m. CST / 1:00 a.m. CET on December 13, 2022
<p>POSTER Management of Canadian Patients (Pts) with Relapsed/Refractory Diffuse Large B-cell Lymphoma (R/R DLBCL) in the Real-World</p>	#1656	Saturday, December 10, 2022 5:30 p.m. CST / 12:30 a.m. CET on December 11, 2022
<p>PUBLICATION Tafasitamab (TAFA) Plus Lenalidomide (LEN) Prior to Chimeric Antigen Receptor T-Cell (CAR-T) Therapy in Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL): Case Series of Eight Patients (Pts)</p>	N/A	N/A
<p>PUBLICATION A Phase 3 Study of Tafasitamab Plus Lenalidomide in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (<i>firm</i>MIND)</p>	N/A	N/A

Please refer to the [ASH online program](#) for full session details and data presentation listings and visit the MorphoSys booth #3115 onsite. MorphoSys is also proud to support a symposium titled “Real-world, real innovation in DLBCL: perspectives on integrating novel antibody platforms into



patient care” on Friday, December 9 from 7:00 a.m. – 9:00 a.m. CST at the Sheraton New Orleans in the Rhythms Ballroom.

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](#).

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.

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 Monjuvi® (tafasitamab-cxix)

Tafasitamab is a humanized Fc-modified CD19 targeting immunotherapy. 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 Europe, the UK and Canada.

XmAb® is a registered trademark of Xencor, Inc.

About L-MIND

The [L-MIND \(NCT02399085\) trial](#) is a single arm, open-label Phase 2 study 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 or refuse subsequent autologous stem cell transplant. 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). In May 2019, the study reached its primary completion.

About frontMIND

The [frontMIND \(NCT04824092\) trial](#) is a randomized, double-blind, placebo-controlled, global Phase 3 clinical study in previously untreated high-intermediate and high-risk DLBCL patients that is conducted in partnership with the German Lymphoma Association (GLA), the Italian Lymphoma study group and the US Oncology Network.

The study aims to enroll approximately 880 DLBCL patients to receive either tafasitamab plus lenalidomide in addition to rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) or R-CHOP alone. The primary endpoint is investigator-assessed progression-free survival, according to Lugano 2014 criteria, and key secondary endpoints include event-free survival by investigator, overall survival, metabolic complete response rate by a Blinded Independent Review Committee, and overall response rate.

About firstMIND

The [firstMIND \(NCT04134936\) trial](#) is a Phase 1b, randomized study of tafasitamab + R-CHOP (Arm A) or tafasitamab + lenalidomide + R-CHOP (Arm B) in patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL). The study includes a safety run-in phase and a main phase (n=66). In the safety run-in phase, 24 patients were enrolled. The primary objective is to assess safety; secondary objectives include objective response rate, PET negative complete response (PET-CR) rate at end of treatment, progression-free survival, event-free survival, long-term safety, pharmacokinetics and immunogenicity of tafasitamab.

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.

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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