



Media Release

Planegg/Munich, Germany, September 12, 2023

MorphoSys Receives U.S. FDA Fast Track Designation for Tulumimetostat in Endometrial Cancer

Tulumimetostat follows pelabresib (2018) and tafasitamab (2014) as the company's third clinical program to receive Fast Track designation

MorphoSys AG (FSE: MOR; NASDAQ: MOR) today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for tulumimetostat, the company's investigational next-generation dual inhibitor of EZH2 and EZH1, for the treatment of patients with advanced, recurrent or metastatic endometrial cancer harboring AT-rich interacting domain containing protein 1A (*ARID1A*) mutations and who have progressed on at least one prior line of treatment. The FDA grants Fast Track designation to facilitate the development and expedite the review of medicines intended to treat serious conditions and potentially address an unmet medical need, with the goal of getting these important, new therapies to patients earlier.

Tulumimetostat 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. The Fast Track designation in endometrial cancer was granted based on preclinical results and preliminary clinical data from an ongoing Phase 1/2 study. This study is investigating tulumimetostat as a monotherapy in patients with advanced solid tumors or lymphomas, including *ARID1A*-mutated endometrial carcinoma and ovarian clear cell carcinoma, diffuse large B-cell lymphoma, peripheral T-cell lymphoma, *BAP1*-mutated mesothelioma and castration-resistant prostate cancer. Updated results were presented at the [2023 American Society of Clinical Oncology \(ASCO\) Annual Meeting](#) in June.

"Receiving Fast Track designation from the FDA for tulumimetostat in *ARID1A*-mutated endometrial cancer underscores this investigational therapy's potential in a patient population with limited treatment options," said Tim Demuth, M.D., Ph.D., MorphoSys Chief Research and Development Officer. "The preliminary results from our Phase 1/2 study of tulumimetostat are very promising. We will continue to generate data from this study across tumor types to inform our future development plans for tulumimetostat, both as a monotherapy and in combination with other treatments."

Tulumimetostat is MorphoSys' third clinical program to receive Fast Track designation from the FDA. Pelabresib, an investigational BET inhibitor, received Fast Track designation for myelofibrosis in 2018, and tafasitamab, a CD19-targeting immunotherapy, received this designation for relapsed or refractory diffuse large B-cell lymphoma in 2014.

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 at X](#) and [LinkedIn](#).

About Tulumimetostat

Tulumimetostat (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. Tulumimetostat 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 objectives of the trial include determining the maximum tolerated dose and/or recommended Phase 2 dose and evaluating antitumor activity of tulmimetostat monotherapy. The safety and efficacy of tulmimetostat have not been established.

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. Its safety and efficacy have also not been established in a pivotal trial.

The development of pelabresib was funded in part by Leukemia and Lymphoma Society.

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). Please see the [U.S. full Prescribing Information](#) for Monjuvi for important safety information.

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. Its safety and efficacy for these investigational uses have not been established in pivotal 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.

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.

For more information, please contact:

Media Contacts:

Thomas Biegi

Vice President

Tel.: +49 (0)89 / 89927 26079

thomas.biegi@morphosys.com

Eamonn Nolan

Director

Tel: +1 617-548-9271

eamonn.nolan@morphosys.com

Investor Contacts:

Dr. Julia Neugebauer

Head of Investor Relations

Tel: +49 (0)89 / 899 27 179

julia.neugebauer@morphosys.com