Pfizer, MorphoSys and Incyte Enter into Clinical Trial Collaboration for Monjuvi® (tafasitamab-cxix) in Combination with TTI-622, a Fusion Protein Directed Against CD47

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NEW YORK & BOSTON & WILMINGTON, Del.--(BUSINESS WIRE)--Pfizer Inc. (NASDAQ:PFE), MorphoSys U.S. Inc., a fully owned subsidiary of MorphoSys AG (FSE: MOR; NASDAQ:MOR), and Incyte (NASDAQ:INCY) today announced a clinical trial collaboration and supply agreement to investigate the immunotherapeutic combination of Pfizer's TTI-622, a novel SIRPα-Fc fusion protein, and Monjuvi® (tafasitamab-cxix) plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplantation (ASCT).

"TTI-622 blocks the signal-regulatory protein (SIRP)α–CD47 axis, which is a key checkpoint expected to become an important backbone immunotherapy across multiple tumors, especially hematological cancers," said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. "The early results for TTI-622 in late-line advanced lymphoid malignancies reflect the potential for class-leading monotherapy activity, and preclinical evidence with a diverse set of therapeutic agents provide a strong rationale for testing combination therapies. We are pleased to collaborate with MorphoSys and Incyte, generating additional evidence on the potential of TTI-622 to improve outcomes for patients with DLBCL."

"Monjuvi in combination with lenalidomide is an important treatment option for patients with relapsed or refractory diffuse large B-cell lymphoma, and its mechanism of action, efficacy and safety profile make it an attractive combination partner," said Malte Peters, M.D., MorphoSys Chief Research and Development Officer. "We believe that the addition of novel immunotherapies, such as the investigational anti-CD47 blocking agent TTI-622, to the backbone of Monjuvi plus lenalidomide have the potential to provide new meaningful combination treatment options for patients with relapsed or refractory diffuse large B-cell lymphoma."

"This collaboration has the potential to advance patient care in an area where there continues to be significant unmet medical need," said Lance Leopold, M.D., Group Vice President, Clinical Development Hematology and Oncology at Incyte. "We are proud to support this research effort to evaluate the potential of a new chemotherapy-free combination for these patients."

Pfizer's TTI-622 is currently in Phase 1b/2 development across several indications, with a focus on hematological malignancies. CD47 is an innate immune checkpoint that binds SIRPα and delivers a "don't eat me" signal to suppress macrophage phagocytosis. Overexpression of CD47 in solid and hematological malignancies, including in DLBCL, is associated with poor prognosis.

Monjuvi (marketed ex-U.S. as Minjuvi®), a CD19-directed immunotherapy, in combination with lenalidomide is a treatment for adult patients with relapsed or refractory DLBCL not otherwise specified, and who are not eligible for ASCT. In this indication, accelerated or conditional approvals were granted by the U.S. Food and Drug Administration, the European Medicines Agency and other regulatory authorities. Monjuvi is being co-commercialized by MorphoSys and Incyte in the United States. Incyte has exclusive commercialization rights outside the United States.

Preclinical data by Morphosys have shown a strong synergy of Monjuvi and anti-CD47 antibodies in in vitro and in vivo lymphoma models, providing scientific rationale for investigating this combination in clinical trials. This preclinical data was presented at the 62nd American Society of Hematology (ASH) Annual Meeting & Exposition in 2020.

Under the terms of the agreement, Pfizer will initiate a multicenter, international Phase 1b/2 study of TTI-622 with Monjuvi and lenalidomide for patients with relapsed or refractory DLBCL who are not eligible for ASCT. MorphoSys and Incyte will provide Monjuvi for the study, which will be sponsored and funded by Pfizer and is planned to be conducted in North America, Europe and Asia-Pacific.

The collaboration is effective immediately upon the execution of the agreement.

About Tafasitamab
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.

XmAb® is a registered trademark of Xencor, Inc.

About Pfizer Oncology
At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 24 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com . In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News , LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer .

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 Incyte
Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte .

Pfizer Forward-looking Statements
The information contained in this release is as of June 13, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about TTI-622 and a clinical trial collaboration and supply agreement to investigate the novel immunotherapeutic combination of TTI-622 and Monjuvi® (tafasitamab-cxix) plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when applications may be filed in any jurisdictions for any potential indications for TTI-622 or the combination of TTI-622 and Monjuvi plus lenalidomide; whether and when regulatory authorities in any jurisdictions may approve any such applications for TTI-622 or the combination of TTI-622 and Monjuvi plus lenalidomide, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether TTI-622 or the combination of TTI-622 and Monjuvi plus lenalidomide will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of TTI-622 or the combination of TTI-622 and Monjuvi plus lenalidomide; whether our clinical trial collaboration and supply agreement with MorphoSys AG and Incyte will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com .

MorphoSys 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.

Incyte Forward-looking Statements
Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the clinical trial collaboration entered into by Pfizer, MorphoSys and Incyte, the planned clinical trials of Monjuvi in combination with lenalidomide and TTI-622, and whether and when such proposed combination might provide a successful treatment option for patients with relapsed or refractory DLBCL, contain

predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte's clinical trials, supply chain and other third-party providers and development and discovery operations; Incyte's dependence on its relationships with its collaboration partners; determinations made by the U.S. FDA and other regulatory authorities outside of the United States; the efficacy or safety of Incyte's products and the products of Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended March 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

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