



Incyte and MorphoSys Announce the Validation of the European Marketing Authorization Application for Tafasitamab

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- The MAA seeks approval of tafasitamab in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma

WILMINGTON, Del.--(BUSINESS WIRE)--May 20, 2020-- Incyte (NASDAQ:INCY) and MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ:MOR) today announced the validation of the European Marketing Authorization Application (MAA) for tafasitamab, an anti-CD19 antibody. The application seeks approval of tafasitamab in combination with lenalidomide, followed by tafasitamab monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), including DLBCL arising from low grade lymphoma, who are not candidates for autologous stem cell transplantation (ASCT). The validation of the MAA by the European Medicines Agency (EMA) confirms that the submission is ready to enter the formal review process.

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"The EMA's validation of the MAA for tafasitamab is a critical step on the path to making tafasitamab available for use in combination with lenalidomide in eligible patients with r/r DLBCL in Europe," said Peter Langmuir, M.D., Group Vice President, Targeted Therapeutics, Incyte. "We will continue to work closely with the EMA to progress the review of this application, with the hope of bringing this novel therapy to eligible patients as soon as possible."

"We are pleased to have achieved this important milestone, which moves tafasitamab in combination with lenalidomide into the formal regulatory review process in the European Union," said Dr. Malte Peters, Chief Research & Development Officer, MorphoSys. "Following the U.S. FDA's acceptance of our Biologics License Application filing for tafasitamab for Priority Review earlier this year, this represents another major step forward. We look forward to continuing to work with the regulatory authorities alongside our partners at Incyte to bring this novel therapeutic option to eligible patients in need."

The MAA, submitted by MorphoSys, is based on data from the L-MIND study evaluating tafasitamab in combination with lenalidomide as a treatment for patients with r/r DLBCL; and is supported by the Re-MIND study, an observational retrospective study in r/r DLBCL. If approved, Incyte will hold the marketing authorization, and has exclusive commercialization rights for tafasitamab outside of the United States, including Europe.

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide – comprising 40% of all cases¹. It is an aggressive disease affecting the B-cells of the immune system with 30-40% of patients who do not respond to initial therapy or relapse thereafter, leading to a high medical need for new, effective therapies².

About L-MIND

The L-MIND trial is 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 (r/r DLBCL) after up to two prior lines of therapy, including an anti-CD20 targeting therapy (e.g. rituximab), who are not eligible for high-dose chemotherapy and subsequent autologous stem cell transplantation. The study's primary endpoint is objective 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. Two-year data, assessed by an independent review committee (November 30, 2019 cut-off), evaluating 80 patients receiving tafasitamab and lenalidomide corroborate previously reported primary analysis data.

For more information about L-MIND, visit <https://clinicaltrials.gov/ct2/show/NCT02399085>.

About Re-MIND

Re-MIND, an observational retrospective study (NCT04150328), was designed to isolate the contribution of tafasitamab in the combination with lenalidomide and to prove the combinatorial effect. The study compares real-world response data of patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) who received lenalidomide monotherapy with the efficacy outcomes of the tafasitamab-lenalidomide combination, as investigated in MorphoSys' L-MIND trial. Re-MIND collected the efficacy data from 490 r/r DLBCL patients in the U.S. and EU. Qualification criteria for matching patients of both studies were pre-specified. As a result, 76 eligible Re-MIND patients were identified and matched 1:1 to 76 of 80 L-MIND patients based on important baseline characteristics. Objective response rates (ORR) were validated based on this subset of 76 patients in Re-MIND and L-MIND, respectively. The primary endpoint of Re-MIND was met and shows a statistically significant superior best ORR of the tafasitamab/lenalidomide combination compared to lenalidomide monotherapy.

For more information about Re-MIND, visit <https://clinicaltrials.gov/ct2/show/NCT04150328>.

About Tafasitamab

Tafasitamab is an investigational humanized Fc-engineered monoclonal antibody directed against CD19. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb(R) engineered Fc domain, which is intended to lead to a significant potentiation of antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), thus aiming to improve a key mechanism of tumor cell killing.

In January 2020, MorphoSys and Incyte entered into a collaboration and licensing agreement to further develop and commercialize tafasitamab globally. If approved, MorphoSys and Incyte will co-commercialize tafasitamab in the United States. Incyte has exclusive commercialization rights outside the United States.

Tafasitamab is being studied as a therapeutic option in B-cell malignancies in a number of ongoing combination trials, including L-MIND and Re-MIND, as well as the ongoing Phase 3 B-MIND study evaluating the combination of tafasitamab and bendamustine versus rituximab and bendamustine in r/r DLBCL. In addition, tafasitamab is currently being evaluated in patients with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after discontinuation of a prior Bruton tyrosine kinase (BTK) inhibitor therapy (e.g. ibrutinib) in combination with idelalisib or venetoclax.

XmAb[®] is a trademark of Xencor, Inc.

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](https://twitter.com/Incyte).

About MorphoSys

MorphoSys is a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization of exceptional, innovative therapies for patients suffering from serious diseases. The focus is on cancer. Based on its leading expertise in antibody, protein and peptide technologies, MorphoSys, together with its partners, has developed and contributed to the development of more than 100 product candidates, 28 of which are currently in clinical development. In 2017, Tremfya[®], marketed by Janssen for the treatment of plaque psoriasis, became the first drug based on MorphoSys' antibody technology to receive regulatory approval. Headquartered near Munich, Germany, the MorphoSys group, including the fully owned U.S. subsidiary MorphoSys US Inc., has over 400 employees. More information at www.morphosys.com.

Incyte Forward-looking Statements

Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: whether tafasitamab will be approved for use in humans anywhere in Europe, the U.S. or elsewhere or will be commercialized in Europe, the U.S. or elsewhere successfully or at all; whether tafasitamab will be effective in the treatment of the indications discussed in this press release; and the expectations, timing and potential results of further development activities involving tafasitamab. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: obtaining regulatory approval for this planned collaboration; research and development efforts related to the collaboration programs; the possibility that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; other market or economic factors, including other scientific developments; unanticipated delays; the effects of market competition; risks associated with relationships between collaboration partners; the impact of governmental actions regarding pricing, importation and reimbursement for pharmaceuticals; and such other risks detailed from time to time in each company's reports filed with the Securities and Exchange Commission, including Incyte's annual report on Form 10-Q for the quarter ending March 31, 2020 and MorphoSys' Annual Report on Form 20-F for the fiscal year ended December 31, 2019. Each party disclaims any intent or obligation to update these forward-looking statements.

MorphoSys Forward-looking Statements

This communication contains certain forward-looking statements concerning the MorphoSys group of companies, including the expectations regarding the licensing agreements for tafasitamab, the further clinical development of Tafasitamab including the L-MIND and Re-MIND studies, interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for tafasitamab as well as the potential future commercialization of tafasitamab. 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 MorphoSys' expectations regarding the licensing agreements for tafasitamab, the further clinical development of tafasitamab including the L-MIND and Re-MIND studies, interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for tafasitamab as well as the potential future commercialization of tafasitamab, 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 US 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.

References

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