



MorphoSys and Incyte Announce Long-term Follow-up Results from L-MIND Study of Tafasitamab in Patients with r/r DLBCL

May 14, 2020

- *New two-year follow-up data (November 30, 2019 cut-off) of L-MIND trial corroborate previously reported primary analysis*
- *Updated IRC efficacy outcomes include objective response rate (ORR) of 58.8%, complete response (CR) rate of 41.3%*
- *Median duration of response (mDOR) of 34.6 months, median progression-free survival (mPFS) of 16.2 months, and median overall survival (mOS) of 31.6 months*
- *Full efficacy and safety data to be presented virtually at the 25th EHA Annual Congress*

MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ:MOR) and Incyte (NASDAQ:INCY) today reported updated results from the ongoing Phase 2 L-MIND study investigating the combination of tafasitamab and lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL). The results, based on a November 30, 2019 data cut-off, corroborate previously reported primary analysis data.

In this long-term analysis of the L-MIND data, 80 study patients receiving tafasitamab plus lenalidomide were included in the efficacy analysis. After a minimum of two years' follow-up, outcomes from the L-MIND study are consistent with the primary analysis and confirm the durability of the response (DoR) and overall survival (OS) of tafasitamab in combination with lenalidomide followed by tafasitamab monotherapy in autologous stem cell transplantation (ASCT)-ineligible patients with r/r DLBCL. Assessment by an independent review committee (IRC) at data cut-off showed an objective response rate (ORR) of 58.8% (47 out of 80 patients) and a complete response (CR) rate of 41.3% (33 out of 80 patients). Median duration of response (mDOR) was 34.6 months, with median overall survival (mOS) of 31.6 months and median progression-free survival (mPFS) of 16.2 months. The safety profile was consistent with that observed in previously reported studies of tafasitamab in combination with lenalidomide. The full analysis will be presented virtually at the 25th EHA Annual Congress to be held June 11-14, 2020.

"We are extremely encouraged by the long-term data from our L-MIND study which confirms the previously reported results from the primary analysis," commented Dr. Malte Peters, Chief Research and Development Officer, MorphoSys. "Tafasitamab in combination with lenalidomide has the potential to address the significant medical need in patients suffering from r/r DLBCL, and we are working diligently towards our key priority of making tafasitamab available to eligible patients."

"The updated data for L-MIND reinforce the potential of tafasitamab in combination with lenalidomide as treatment for patients with r/r DLBCL. We look forward to working with our partners at MorphoSys as we seek to bring this new therapeutic option to eligible patients globally," Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapeutics, Incyte.

A Biologics License Application (BLA) for tafasitamab in combination with lenalidomide for r/r DLBCL is currently under Priority Review by the U.S. Food and Drug Administration (FDA) (PDUFA action date August 30, 2020). The BLA is based on data including the primary analysis of L-MIND with a previous cut-off date as of November 30, 2018, and the primary analysis data from the retrospective observational matched control cohort Re-MIND evaluating efficacy outcomes of r/r DLBCL patients who received lenalidomide monotherapy.

In January 2020, MorphoSys and Incyte Corporation 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 while Incyte has exclusive commercialization rights outside the United States.

About L-MIND

L-MIND 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 (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. Primary analysis data with a cut-off date of November 30, 2018 included 80 patients enrolled into the trial who had received tafasitamab and lenalidomide and had been followed-up as per protocol for at least one year. Efficacy results in this update were based on response rates assessed by an independent review committee for all 80 patients.

About Re-MIND

Re-MIND, an observational retrospective study, 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 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 has been met and shows a statistically significant superior best ORR of the tafasitamab/lenalidomide combination compared to lenalidomide monotherapy.

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 Corporation entered into a collaboration and licensing agreement to further develop and commercialize tafasitamab globally. If approved in the U.S., MorphoSys and Incyte will co-commercialize tafasitamab; Incyte will have exclusive commercialization rights outside the U.S. Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in a number of ongoing combination trials, including L-MIND and Re-MIND. Additionally, tafasitamab is being evaluated as part of the ongoing Phase 3 study B-MIND study assessing the combination of tafasitamab and bendamustine versus rituximab and bendamustine in r/r DLBCL. Tafasitamab is also currently being investigated 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.

About MorphoSys

MorphoSys (FSE & NASDAQ: MOR) 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, 27 of which are currently in clinical development. In 2017, Tremfya(R), marketed by Janssen for the treatment of plaque psoriasis, became the first drug based on MorphoSys' antibody technology to receive regulatory approval. MorphoSys most advanced proprietary product candidate, tafasitamab (MOR208), is in late-stage clinical development for the treatment of patients with relapsed/refractory diffuse large B-cell lymphoma (r/r DLBCL). 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.

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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).

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.

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.

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