Media Release
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Primary Endpoint met in Real-World Data Study Demonstrating Clinical Superiority of the Combination of Tafasitamab and Lenalidomide compared to Lenalidomide alone

- Primary endpoint met: Statistically significant superior best objective response rate seen in combination treatment of tafasitamab with lenalidomide (L-MIND) when compared to a real-world data matched control cohort of lenalidomide alone (Re-MIND)
- Superiority consistently observed across all secondary endpoints and pre-specified statistical sensitivity analyses
- Data support plan to submit BLA for tafasitamab in combination with lenalidomide based on L-MIND study results before end of 2019; rolling submission of BLA initiated

MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; Nasdaq: MOR) today announced topline results from the primary analysis of the retrospective observational matched control cohort (Re-MIND). This study was designed to compare the effectiveness of lenalidomide monotherapy based on real-world patient data with the efficacy outcomes of the tafasitamab/lenalidomide combination, as investigated in MorphoSys's L-MIND trial.

Re-MIND collected outcome data from 490 non-transplant eligible patients with relapsed/ refractory diffuse large B cell lymphoma (r/r DLBCL) who had received lenalidomide monotherapy in the U.S. and the EU in a real-world setting. 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. ORR was 67.1% (95% confidence interval (CI): 55.4-77.5) for the tafasitamab/ lenalidomide combination, compared to 34.2% (CI: 23.7-46.0) for the lenalidomide monotherapy ($p<0.0001$). Superiority was consistently observed across all secondary endpoints, including complete response (CR) rate (tafasitamab/lenalidomide combination 39.5%; CI: 28.4-51.4 versus lenalidomide monotherapy 11.8%; CI: 5.6-21.3; $p<0.0001$), as well as in pre-specified statistical sensitivity analyses. In addition, there was a significant difference observed in overall survival, which was not reached in the tafasitamab/lenalidomide combination as compared to 9.3 months in the lenalidomide monotherapy (hazard ratio 0.47; CI: 0.30-0.73; $p<0.0008$).

“Encouraged by the results we achieved with the real-world data approach, we re-affirm our plans to pursue advancement of tafasitamab to market in combination with lenalidomide as a potential, chemo-free treatment option for patients with r/r DLBCL, subject to FDA approval. The data announced today complement the previously published data of the single-arm L-MIND study and MorphoSys has started the rolling submission of our BLA to the FDA, which we plan to complete by end of this year,” commented Dr. Malte Peters, Chief Development Officer of MorphoSys AG.

“I’m very excited about this real-world data approach of the Re-MIND trial to isolate a single-agent contribution of tafasitamab in combination with lenalidomide in a matched patient population in r/r DLBCL. This study further strengthens the synergistic effect of tafasitamab and lenalidomide, as already observed in the L-MIND trial,” said Pier Luigi Zinzani, M.D., Ph.D., Professor of Hematology, Head of Lymphoma Group, Institute of Hematology, “L. e A. Seràgnoli”, University of Bologna, Bologna, Italy, and one of the lead investigators in MorphoSys's Re-MIND study.

Details of the L-MIND primary analysis were published on June 22, 2019, and can be found here.

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. Based on earlier reported interim data from L-MIND, in October 2017 the U.S. FDA granted Breakthrough Therapy Designation for tafasitamab plus lenalidomide in this patient population. MorphoSys is working towards completion of a BLA submission to the U.S. FDA based on L-MIND by end of 2019.

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’s L-MIND trial. Re-MIND collected the efficacy data from 490 r/r DLBCL patients in the U.S. and EU. Eligible patients were matched 1:1 to the L-MIND study population based on important baseline characteristics, such as relevant prognostic factors, laboratory characteristics and patient demographics.

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, of which 29 are currently in clinical development. In 2017, Tremfya®, marketed by Janssen for the treatment of plaque psoriasis, became the first drug based on MorphoSys's antibody technology to receive regulatory approval. The Company's most advanced proprietary product candidate, tafasitamab, has been granted U.S. FDA breakthrough therapy designation for the treatment of patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). Headquartered near Munich, Germany, the MorphoSys group, including the fully owned U.S. subsidiary MorphoSys US Inc., has approximately 370 employees. More information at https://www.morphosys.com.

MorphoSys forward looking statements

This communication contains certain forward-looking statements concerning the MorphoSys group of companies, including the expectations regarding the outcome of the Re-MIND study, the clinical development of tafasitamab in combination with lenalidomide in the L-MIND study in r/r DLBCL, the clinical development of tafasitamab in combination with bendamustine versus rituximab and bendamustine in the B-MIND study in r/r DLBCL, the further clinical development of tafasitamab as well as interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for 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 outcome of the Re-MIND study, the clinical development of tafasitamab in combination with lenalidomide in the L-MIND study in r/r DLBCL, the clinical development of tafasitamab in combination with bendamustine versus rituximab and bendamustine in the B-MIND study in r/r DLBCL, the further clinical development of tafasitamab as well as interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for 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's 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.

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