Media Release
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MorphoSys Announces Intention to Submit Marketing Authorization Application for Tafasitamab to European Medicines Agency

MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; NASDAQ: MOR) today announced its intention to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) based on its phase 2 L-MIND study of tafasitamab (MOR208) and lenalidomide in relapsed or refractory diffuse large B cell lymphoma (r/r DLBCL). A letter of intent was submitted to EMA in early July and MorphoSys plans to complete the MAA submission by mid-2020.

L-MIND is a single-arm, open-label phase 2 study investigating the antibody tafasitamab in combination with lenalidomide in patients with relapsed or refractory diffuse large B cell lymphoma who are not eligible for high-dose chemotherapy and autologous stem cell transplantation. In July 2019, the company presented positive primary analysis data from L- MIND at the ICML conference in Lugano. These data will form the basis for the planned filing package of the MAA that, if granted, allows for earliest approval in Europe in 2021.

“We are excited about the progress we are making with our plan for a possible regulatory approval for tafasitamab in Europe,” said Dr. Malte Peters, Chief Development Officer at MorphoSys. “The preceding constructive interaction with the European regulatory authorities has given us the confidence to pursue an MAA submission for approval in Europe based on L-MIND. This complements our current focus on seeking approval of tafasitamab in the U.S. on the basis of L-MIND, for which we will complete a BLA submission to the FDA by year-end.”

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 (MOR208), 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 clinical development of tafasitamab in combination with lenalidomide in the L-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 clinical development of tafasitamab in combination with lenalidomide in the L-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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