



## Media Release

Planegg/Munich, Germany, March 7, 2019

### **MorphoSys Provides Updates on L-MIND and B-MIND Clinical Trials of MOR208 in Relapsed/Refractory DLBCL**

MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; Nasdaq: MOR) today provided updates on L-MIND and B-MIND, its two ongoing clinical trials of the investigational Fc-enhanced anti-CD19 antibody MOR208 in patients with relapsed or refractory diffuse large B cell lymphoma (r/r DLBCL), who are not eligible for high-dose chemotherapy and autologous stem cell transplantation.

The L-MIND trial, the Company's single-arm, open-label study investigating MOR208 in combination with lenalidomide, has completed enrollment and data are currently being analyzed. Topline results are expected to be released at a medical conference in mid-2019. The Company intends to use L-MIND as the basis for a regulatory filing to the FDA, which it expects to complete by the end of this year. In parallel, the Company has initiated discussions with National European Regulatory Authorities to explore the possibility of using the L-MIND study as the basis for the submission of a potential marketing authorization application (MAA) in Europe. If the European Medicines Agency (EMA) were to agree to accept a potential MAA based on L-MIND, submission of such an MAA could occur earlier than originally anticipated based on the B-MIND trial. MorphoSys is seeking scientific advice from EMA in the forthcoming months.

The B-MIND study, which compares MOR208 in combination with bendamustine versus rituximab plus bendamustine, continues as originally designed. Additionally, during the first quarter of 2019 and in agreement with the FDA, MorphoSys implemented an amendment of the B-MIND study. The scientific rationale for the amendment is based on published literature as well as MorphoSys's own pre-clinical data, which indicate that MOR208 might be particularly active in patients who can be characterized by the presence of a certain biomarker. The amended B-MIND trial may serve, in addition to being potentially pivotal on its own, as a confirmatory study if conditional approval of MOR208 is granted based on L-MIND. Discussions with the FDA regarding the biomarker assay are currently being planned and are expected to take place in the middle of this year. The pre-planned, event-driven interim analysis of B-MIND remains projected to take place in the second half of 2019. Depending on the outcome of the interim analysis, an increase from 330 to 450 patients may be required, in which case an event-driven primary analysis of the study is expected in the first half of 2021.

"Our L-MIND trial continues as planned and we are on track to completing our regulatory submission to the FDA this year", commented Dr. Malte Peters, Chief Development Officer of Morphosys AG. "Further, we are having early conversations with European regulators about the possibility of using L-MIND as the basis for a filing in Europe. We hope to have a clearer picture of the regulatory path in Europe within the next several months. Following discussions with the FDA, we have introduced a co-primary endpoint into the B-MIND trial based on pre-clinical data that suggest the involvement of a certain biomarker. The amended B-MIND trial enables us to test the hypothesis that MOR208 shows enhanced activity in patients who can be identified using the biomarker, while in addition allowing us to test efficacy in the unselected patient population as originally planned."

### About CD19 and MOR208

CD19 is broadly and homogeneously expressed across different B cell malignancies including DLBCL and CLL. CD19 has been reported to enhance B cell receptor (BCR) signaling, which is assumed important for B cell survival, making CD19 a potential target in B cell malignancies.

MOR208 is an investigational humanized Fc-engineered monoclonal antibody directed against CD19. Fc-modification of MOR208 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. MOR208 has been observed in preclinical models to induce direct apoptosis by binding to CD19, which is assumed to be involved in B cell receptor (BCR) signaling.

MorphoSys is clinically investigating MOR208 as a therapeutic option in B cell malignancies in a number of ongoing combination trials. An open-label phase 2 combination trial (L-MIND study) is investigating the safety and efficacy of MOR208 in combination with lenalidomide in patients with relapsed/refractory DLBCL who are not eligible for high-dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT). Based on interim data from L-MIND, in October 2017 the U.S. FDA granted Breakthrough Therapy Designation for MOR208 plus lenalidomide in this patient population. The pivotal phase 2/3 B-MIND study is designed to investigate MOR208 in combination with the chemotherapeutic agent bendamustine in patients with relapsed/refractory DLBCL who are not eligible for high-dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT) in comparison to the combination of the anti-CD20 antibody rituximab plus bendamustine. In addition, MOR208 is currently being investigated in patients with relapsed/refractory 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, of which 29 are currently in clinical development. In 2017, Tremfya<sup>®</sup>, 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, 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 330 employees. More information at <https://www.morphosys.com>.

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### MorphoSys forward looking statements

*This communication contains certain forward-looking statements concerning the MorphoSys group of companies, including the clinical development of MOR208 in combination with lenalidomide in the L-MIND study in r/r DLBCL, the clinical development of MOR208 in combination with bendamustine versus rituximab and bendamustine in the B-MIND study in r/r DLBCL, the further clinical development of MOR208 as well as interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for MOR208. 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 the clinical development of MOR208 in combination with lenalidomide in the L-MIND study in r/r DLBCL, the clinical development of MOR208 in combination with bendamustine versus rituximab and bendamustine in the B-MIND study in r/r DLBCL, the further clinical development of MOR208 as well as interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for MOR208,, 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 Registration Statement on Form F-1 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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