Media Release
Planegg/Munich, Germany, May 16, 2019

Primary Endpoint of L-MIND, a Combination Study of Tafasitamab (MOR208) and Lenalidomide, has been met, Confirming Previously Published Activity

- Primary analysis of L-MIND trial of tafasitamab (MOR208) plus lenalidomide in relapsed or refractory (r/r) DLBCL confirms overall strong data reported previously from this trial
- Objective response rate (ORR) of 60%, complete response (CR) rate of 43%
- Median progression-free survival (mPFS) of 12.1 months with a median follow-up of 17.3 months indicates a high proportion of patients with a long term treatment effect, supported by a long median duration of response (mDoR) of 21.7 months
- A Q&A session on the headline data to be held on May 20, 2019 at 2:00pm CEST (1:00pm BST/8:00am EDT)

MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; Nasdaq: MOR) today announced results from the primary analysis (cut-off date November 30, 2018) of the ongoing single-arm phase 2 clinical trial known as L-MIND.

The primary endpoint, defined as best ORR compared to published data on the respective monotherapies, has been met. The ORR was 60% (48 out of 80 patients), and the CR rate was 43% (34 out of 80 patients). The mPFS was 12.1 months with a median follow-up of 17.3 months. The mDoR was 21.7 months. These results provide overall confirmation of the strong L-MIND data previously published at ASH in December 2018.

The data reported today 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 are based on response rates assessed by an independent review committee for all 80 patients.

“We are delighted to see that the overall results fom the primary analysis of our L-MIND trial have confirmed the strong data we had presented at ASH in 2018”, commented Dr. Malte Peters, Chief Development Officer of MorphoSys AG. “We strongly believe we have a remarkable drug candidate and these data further support our plan to develop tafasitamab in combination with lenalidomide as a potential chemo-free treatment option for patients with r/r DLBCL. We remain highly committed to completing the submission of a BLA to the FDA by end of this year.”

“The results fom the primary analysis are very encouraging. We are particularly pleased to see such a high complete response rate and a prolonged response duration, which is unsual in this population of relapsed or refractory DLBCL. If approved, given its safety profile, tafasitamab has the potential to become a new treatment option to improve quality of life and outcome for patients with this disease”, says Professor Gilles Salles, Chair of the Clinical Hematology Department at the University of Lyon, France, and lead investigator of L-MIND.

L-MIND is designed to investigate the antibody tafasitamab in combination with lenalidomide 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. Tafasitamab is an investigational humanized Fc-enhanced monoclonal antibody directed against CD19 and is currently in clinical development in blood cancer indications.

MorphoSys's management will be available for a Q&A session on the headline data on Monday, May 20, 2019 at 2:00pm CEST (1:00pm BST/8:00am EDT).

MorphoSys plans to present detailed results at the ICML conference in Lugano in June this year.

Dial-in number for the Q&A session on Monday, May 20, 2019 at 2:00pm CEST; 1:00pm BST; 8:00am EDT:

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About CD19 and tafasitamab (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.

Tafasitamab (MOR208) is an investigational humanized Fc-engineered monoclonal antibody directed against CD19. Fc-modification of tafasitamab 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. Tafasitamab 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 tafasitamab 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 tafasitamab 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 tafasitamab plus lenalidomide in this patient population. The pivotal phase 2/3 B-MIND study is designed to investigate tafasitamab 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, tafasitamab 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®, 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 330 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 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 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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