Media Release
Planegg/Munich, Germany, June 2, 2017

MorphoSys Starts Phase 3 Trial of MOR208 plus Bendamustine in Patients with Relapsed or Refractory DLBCL

First pivotal study with compound from MorphoSys's proprietary portfolio started, following IDMC recommendation after initial safety evaluation

MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) announced today that the pivotal phase 3 part of the B-MIND clinical study of MOR208 has been opened for enrollment. The randomized, multicenter phase 2/3 study is designed to investigate the efficacy of MOR208 plus bendamustine versus rituximab plus bendamustine in patients with relapsed or refractory diffuse large B cell lymphoma (R/R DLBCL) who are not eligible for high-dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT). DLBCL is the most common form of non-Hodgkin's lymphoma. MOR208 is an investigational, Fc-enhanced monoclonal antibody directed against CD19 and is being developed for the treatment of patients with B cell malignancies.

"We are delighted that MOR208, as the first antibody from MorphoSys's proprietary pipeline, has started pivotal phase 3 development," commented Dr. Malte Peters, Chief Development Officer of MorphoSys AG. "For patients with relapsed or refractory DLBCL who are not eligible for HDC and ASCT, current treatment options are limited. In our pivotal B-MIND study, we are therefore exploring MOR208 in combination with bendamustine, as a potential treatment alternative for this difficult-to-treat patient group".

Based on the available data from the phase 2 safety evaluation part of the B-MIND trial, the Independent Data Monitoring Committee (IDMC) supported the continuation of the trial as per protocol and the transition of the study into its pivotal phase 3 part.

Patients must have been treated previously with at least one but not more than three prior lines of therapy, including one anti-CD20 targeted therapy. The study is expected to enroll a total of approximately 330 patients in about 180 centers in Europe, Asia Pacific (APAC) and the USA.

The dosing of the first patient in the phase 3 part will trigger an undisclosed milestone payment to Xencor, Inc., from whom MOR208 was in-licensed in 2010. MorphoSys has worldwide rights to MOR208.

Detailed information on the trial can be found at ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT02763319).

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 (previously Xmab®5574) is an Fc-enhanced 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. Furthermore, MOR208 has been observed in preclinical models to induce direct apoptosis by binding to CD19, which is assumed to be a crucial component for B cell receptor (BCR) signaling.

MorphoSys AG is clinically investigating MOR208 as a therapeutic option in B cell malignancies in a number of ongoing combination trials. A phase 2 combination trial (L-MIND study) started in March 2016 and is designed to investigate the safety and efficacy of MOR208 in combination with lenalidomide in approximately 80 patients with relapsed/refractory DLBCL. The phase 2/3 B-MIND study was started in August 2016 and transitioned into its phase 3 pivotal part in June 2017 following a recommendation of the IDMC based on the available data from the phase 2 initial safety evaluation. The B-MIND study is designed to investigate MOR208 in combination with the chemotherapeutic agent bendamustine in relapsed/refractory DLBCL patients 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. Furthermore, in December 2016, a third phase 2 combination trial (COSMOS study) was started with MOR208 evaluating the antibody in patients with relapsed/refractory CLL after discontinuation of a prior Bruton tyrosine kinase (BTK) inhibitor therapy (e.g. ibrutinib). Currently MOR208 is being studied in combination with idelalisib; a second study arm of MOR208 plus venetoclax is currently in preparation.

About MorphoSys

MorphoSys is committed to developing exceptional new treatments for patients suffering from serious diseases. A leader in the field of therapeutic antibodies today, MorphoSys is driven by the ambition of creating the most valuable pipeline of biopharmaceuticals in the biotechnology industry. Based on its proprietary technology platforms, MorphoSys, together with its partners, has built a therapeutic pipeline of more than 110 programs in R&D, around a quarter of which is currently in clinical development.
In its proprietary development segment, MorphoSys, alone or with partners, is developing new therapeutic candidates, mainly focusing on cancer and inflammation. In its partnered discovery segment, MorphoSys uses its technologies to discover new drug candidates for pharmaceutical partners and participates from the programs' further development success, through success-based payments and royalties. MorphoSys is listed on the Frankfurt Stock Exchange under the symbol MOR. For regular updates about MorphoSys, visit http://www.morphosys.com.

This communication contains certain forward-looking statements concerning the MorphoSys group of companies. The forward-looking statements contained herein represent the judgment of MorphoSys as of the date of this release and involve risks and uncertainties. Should actual conditions differ from the Company's assumptions, actual results and actions may differ from those anticipated, MorphoSys does not intend to update any of these forward-looking statements as far as the wording of the relevant press release is concerned.

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