MorphoSys Initiates Phase 2/3 Trial of CD19 Antibody MOR208 plus Bendamustine in Patients with Relapsed or Refractory DLBCL

MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) announced today that the first patient has been dosed in the safety evaluation phase of a phase 2/3 combination trial of MOR208 with bendamustine. The B-MIND trial (Bendamustine-MOR208 IN DLBCL) will evaluate the safety and efficacy of MOR208 combined with the chemotherapeutic agent bendamustine in comparison to rituximab plus bendamustine. The randomized international study will enroll adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplantation. DLBCL is the most common form of non-Hodgkin's lymphoma (NHL). Following the phase 2 safety evaluation part, the study is expected to be transitioned into a pivotal phase 3 part in 2017. The investigational drug MOR208 is an Fc-enhanced monoclonal antibody targeting CD19, and is being developed for the treatment of patients with B cell malignancies.

"We are truly excited to begin the phase 2/3 B-MIND trial with MOR208 in DLBCL, which we aim to transition into MorphoSys's first pivotal study with an antibody from our proprietary pipeline next year. CD19 is a potential target in B cell malignancies and, coupled with MOR208’s proprietary antibody design, we aim at developing MOR208 as a new treatment option for patients with a high unmet medical need," said Dr. Arndt Schottelius, Chief Development Officer of MorphoSys. "With the start of the B-MIND clinical trial, we now have two combination studies ongoing with MOR208 in relapsed/refractory DLBCL. We are encouraged by the results we have seen so far in patients treated with MOR208 as a single agent in our earlier clinical trials and we look forward to more data coming from our combination trials."

The randomized, double-arm, open-label, multicenter phase 2/3 B-MIND study is expected to enroll approximately 330 patients in about 180 centers in Europe, Asia Pacific (APAC) and the USA. At the time of study entry, patients must present with relapsed or refractory DLBCL, which has previously been treated with at least one and not more than three prior lines of therapy, including one anti-CD20 targeting therapy (e.g. rituximab). Patients must not be eligible for high-dose chemotherapy and autologous stem cell transplantation.

The phase 2 safety evaluation part of the study will assess the safety and tolerability of MOR208 plus bendamustine vs. the rituximab plus bendamustine combination, enrolling approximately 10 patients in each treatment arm.

Following the safety evaluation part, the trial is intended to be transitioned into the pivotal phase 3 part, expected to start in 2017. The primary endpoint of the study is progression-free survival (PFS). Secondary outcome measures will include objective response rate (ORR), duration of response (DoR), overall survival (OS), disease control rate (DCR), time to progression (TTP) as well as an evaluation of patients’ quality of life (QoL).
Detailed information on the trial can be found at clinicaltrials.gov.

About CD19
CD19 is broadly and homogeneously expressed across different B cell malignancies including DLBCL and CLL. CD19 enhances B cell receptor (BCR) signaling, which is important for B cell survival, making CD19 a potential target in B cell malignancies.

About MOR208
MOR208 (previously Xmab®5574) is an Fc-enhanced monoclonal antibody targeting 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 possibly improving a key mechanism of tumor cell killing. Furthermore, MOR208 induces direct apoptosis by binding to CD19, which is a crucial component for B cell receptor (BCR) signaling.
MorphoSys AG is investigating MOR208 as an immunotherapeutic option in B cell malignancies.
Updated data, presented at the 2016 annual meetings of the American Society of Clinical Oncology (ASCO) and European Hematology Association (EHA), presented the safety and efficacy results of an open-label study of MOR208 as monotherapy in 92 heavily pre-treated NHL patients (non-Hodgkin’s lymphoma). The overall response rate (ORR) in evaluable patients was 36% in the diffuse large B cell lymphoma (DLBCL) and 33% in indolent NHL (iNHL) patients. At the time of the analysis, the median duration of response (DoR) (Kaplan-Meier estimates) in DLBCL was 20 months with three ongoing responses. Median DoR was not reached in iNHL patients with 72% of responders without disease progression at 16 months. The 12-months PFS rate in DLBCL was 40% with similar PFS in both rituximab-sensitive and -refractory patients. The incidence of grade 3 or higher hematologic treatment-emergent adverse events was 26% in DLBCL and 9% in iNHL. Infusion-related reactions were seen in 9% of patients with DLBCL and iNHL, respectively. No treatment-related deaths were reported.

About MorphoSys:
MorphoSys developed HuCAL, the most successful antibody library technology in the pharmaceutical industry. By successfully applying this and other patented technologies, MorphoSys has become a leader in the field of therapeutic antibodies, one of the fastest-growing drug classes in human healthcare.
Together with its pharmaceutical partners, MorphoSys has built a therapeutic pipeline of more than 100 human antibody drug candidates for the treatment of cancer, rheumatoid arthritis, and Alzheimer’s disease, to name just a few. With its ongoing commitment to new antibody technology and drug development, MorphoSys is focused on making the healthcare products of tomorrow. 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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