Media Release
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MorphoSys Receives FDA Breakthrough Therapy Designation for Its Antibody MOR208 in Relapsed/Refractory DLBCL

Designation is intended to expedite development of MorphoSys's most advanced blood cancer drug candidate MOR208 in combination with cancer drug lenalidomide

MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to MOR208, in combination with lenalidomide, for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who are not eligible for high-dose chemotherapy and autologous stem-cell transplantation. MOR208 is an investigational Fc-engineered monoclonal antibody directed against CD19 which is currently in clinical development in blood cancer indications.

FDA Breakthrough Therapy designation is intended to expedite development and review of drug candidates, alone or in combination with other drugs. It is granted if preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies in the treatment of a serious or life-threatening disease.

DLBCL is the most frequent type of malignant lymphoma worldwide and accounts for approximately 30% of all non-Hodgkin lymphomas. Between 30% and 40% of all patients with DLBCL either fail to respond to or show a relapse to initial therapy.

"DLBCL is a very aggressive lymphoma. In particular, those patients who fail standard treatments are in need of more therapeutic options. We look forward to working closely with the FDA and to develop MOR208 as a potential new treatment option for these patients as quickly as possible," said Dr. Malte Peters, Chief Development Officer of MorphoSys AG.

FDA's Breakthrough Therapy designation is based on preliminary data from the ongoing phase 2 L-MIND study (NCT02399085), which is evaluating the safety and efficacy of MOR208 in combination with lenalidomide in patients with R/R DLBCL who are ineligible for high-dose chemotherapy and autologous stem cell transplantation. Preliminary data based on 34 eligible patients presented at ASCO 2017, showed an objective response rate (ORR) of 56% and a complete response rate of 32%.

"For MorphoSys, relapsed/refractory DLBCL is a key development focus. We expect to report further data from our ongoing phase 2 L-MIND trial with MOR208 plus lenalidomide at this year's American Society of Hematology conference in December. In addition, we are currently evaluating MOR208 in combination with bendamustine in our phase 3 B-MIND trial. MorphoSys intends to speed up and potentially broaden the development of MOR208 in other indications of unmet need," Dr. Peters continued.

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 investigational 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. An open-label phase 2 combination trial (L-MIND study) was started in March 2016 and is designed to investigate the safety and efficacy of MOR208 in combination with lenalidomide in 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 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. Furthermore, MOR208 is currently being clinically investigated in patients with relapsed/refractory CLL after discontinuation of a prior Bruton tyrosine kinase (BTK) inhibitor therapy (e.g. ibrutinib) in combination with idelalisib or venetoclax.

About MorphoSys

MorphoSys's mission is to make exceptional, innovative biopharmaceuticals to improve the lives of patients suffering from serious diseases. Innovative technologies and smart development strategies are central to our approach. Success is created by our people, who focus on excellence in all they do, collaborate closely across disciplines and are driven by a desire to make the medicines of tomorrow a reality. Success benefits all of our stakeholders. Based on its proprietary technology platforms, particularly in the field of fully human therapeutic antibodies, 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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