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MorphoSys and Xencor Report Clinical Data for MOR208/XmAb5574 - Phase 1/2a Trial in CLL/SLL Patients Met Primary and Secondary Objectives

MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX) and US-based Xencor, Inc. today announced the online publication of first clinical data on the anti-CD19 antibody MOR208 (MOR00208/XmAb5574) in the American Society of Hematology Annual Meeting Abstracts issue of the peer-reviewed medical journal Blood. MOR208 showed encouraging signs of preliminary anti-tumor activity and an acceptable safety and tolerability profile in patients with high-risk, heavily pretreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). The data support further development of the compound. Based on these results, MorphoSys plans to commence phase 2 studies of MOR208 in B-cell malignancies in the near future.

"We are very pleased with the data which justify advancing into phase 2 development in B-cell malignancies," commented Dr. Arndt Schottelius, Chief Development Officer of MorphoSys AG. "Given that the participants in the trial had received a median of four prior therapies, the overall response rate that we observed is very encouraging. In addition, the favorable toxicity profile will potentially allow combinations with other active agents. The results of the phase 1/2a study show us that we are on the right track with our most advanced proprietary compound in cancer."

The phase 1/2a trial was designed to assess the drug's safety, tolerability, pharmacokinetic profile and preliminary anti-tumor activity. MOR208 was administered as an intravenous infusion on days 1, 4, 8, 15, and 22 of cycle 1, and on days 1, 8, 15, and 22 of cycle 2. Dose levels tested ranged from 0.3 to 12 mg/kg. Among the 27 evaluable patients, three partial responses were observed at the 6, 9, and 12 mg/kg dose levels. In addition, 22 patients experienced stable disease and only two patients progressed at the 8 week evaluation point. Clinical responses were assessed according to International Working Group on CLL (IWCLL) 2008 and 1996 Guidelines. Overall response rate by IWCLL 2008 criteria was 11% which utilizes more rigorous CT scan reduction of internal lymph nodes not previously required in older historic studies. Using IWCLL 1996 response criteria resulted in a response rate of 42%. The most common adverse events were mild to moderate infusion reactions usually with the first dose. Treatment-related adverse events classified as grade 3 or higher occurred in 5 out of 27 patients. Only one dose-limiting toxicity was observed in 16 patients treated at the 12 mg/kg dose level and the trial protocol was amended to include a period of extended dosing with a total of 8 patients at this dose.

"MOR208 was safe and well-tolerated in this first-in-human study, and shows promise as an novel immunotherapy for B-cell malignancies", commented the principal investigator of the study John C. Byrd, MD, Professor and D Warren Brown Chair of Leukemia Research at The James Cancer Hospital and Solove Research Institute. "We are really looking forward to incorporating this together with other active immune and targeted therapies used for CLL in the near future".

Final phase 1/2a data will be presented at the 2012 American Society of Hematology (ASH) annual meeting from December 8-11, 2012 in Atlanta.

"MOR208 is now well positioned to advance in development into additional B-cell malignancies," said Bassil Dahiyat, Ph.D., Chief Executive Officer of Xencor. "The combination of tolerability and anti-tumor activity add to the growing body of clinical data on our XmAb® technology for enhancing antibody cytotoxic potency."

In June 2010, MorphoSys AG and Xencor signed a worldwide exclusive license and collaboration agreement. The agreement provided MorphoSys with an exclusive worldwide license to MOR208 for the treatment of cancer and other indications. Using Xencor's XmAb® Fc enhancement technology, MOR208 has been engineered to possess significantly enhanced antibody-dependent cell-mediated cytotoxicity (ADCC), thus improving a key mechanism for tumor cell killing and offering potential for enhanced efficacy compared to traditional antibodies for the treatment of cancer. MorphoSys will be solely responsible for further clinical development after successful completion of the phase 1/2a clinical trial. MorphoSys plans to initiate additional clinical trials for MOR208 in non-Hodgkin's lymphoma (NHL) and acute lymphoblastic leukemia (ALL) by year-end.

The full abstract is available on bloodjournal.hematologylibrary.org

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. The company's AbD Serotec unit uses HuCAL and other antibody technologies to generate superior monoclonal antibodies for research and diagnostic applications.

Together with its pharmaceutical partners, MorphoSys has built a therapeutic pipeline of more than 70 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 www.morphosys.com

About Xencor, Inc.
Xencor, Inc. engineers superior biotherapeutics using its proprietary Protein Design Automation® technology platform, and is a leader in the field of antibody engineering to significantly improve antibody half-life, immune-regulatory function and potency. The company is advancing multiple XmAb® antibody drug candidates in the clinic, including XmAb®5871 targeting CD32b and CD19 for autoimmune diseases, and an anti-CD30 candidate XmAb®2513 for the treatment of Hodgkin's lymphoma. Xencor is also advancing a portfolio of biosuperior versions of blockbuster antibody drugs engineered for superior half-life and dosing schedule. Xencor has entered into multiple partnerships with industry leaders such as Amgen, Pfizer, Centocor, MorphoSys, Boehringer Ingelheim, CSL Ltd. and Human Genome Sciences. In these partnerships Xencor is applying its suite of proprietary antibody Fc domains to improve antibody drug candidates for traits such as sustained half-life and/or potency. More information is available at www.xencor.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.

For more information, please contact:

Xencor, Inc.
Heidi Chokeir, Ph.D.
Canale Communications for Xencor
heidi@canalecomm.com
(619)849-5377

MorphoSys AG
Dr. Claudia Gutjahr-Löser
Head of Corporate Communications & IR
Tel: +49 (0) 89 / 899 27-122

Mario Brkulj
Senior Manager Corporate Communications & IR
Tel: +49 (0) 89 / 899 27-454

Alexandra Goller
Specialist Corporate Communications & IR
Tel: +49 (0) 89 / 899 27-332

investors@morphosys.com