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MorphoSys and Xencor Publish Final Results from Phase 1/2a Trial of MOR208 (XmAb5574) in CLL/SLL at ASH Annual Meeting

Results Show Durable Responses in High Risk Patient Population

MARTINSRIED, Germany, MUNICH and MONROVIA, Calif., Dec. 6, 2014 /PRNewswire/ -- MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX, OTC: MPSYY) and Xencor Inc. (NASDAQ: XNCR) today announced the publication of final results of a Phase 1/2a trial evaluating MOR208 (formerly XmAb5574) in patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL). MOR208 is a potent anti-CD19 antibody with a proprietary modification to the Fc portion that is being developed to treat B-cell malignancies. MOR208 was in-licensed by MorphoSys from Xencor in 2010.

The results demonstrate that the drug was well tolerated and achieved durable responses in a high risk and poor prognosis patient population with significant progression-free survival achieved:

- At recommended dose 12 patients (75%) had a partial response by physical exam criteria (IWCLL1996) and 6 patients (37.5%) had a partial response using additional CT criteria (IWCLL2008)
- Blood disease cleared in most patients, with median reduction in absolute lymphocyte count from baseline of 90.8%
- Progression-free survival of up to 60 weeks for patients in extended treatment arm

"The data presented by the Ohio State University and our collaboration partner Xencor complement the clinical results we will present tomorrow at ASH for MOR208 in NHL. In the meantime, phase 2 clinical evaluation of MOR208 in CLL in combination with lenalidomide as well as in NHL and ALL is ongoing. Taken together the MOR208 program has advanced significantly in 2014 and the clinical evidence supporting this program is stronger than ever," commented Dr. Arndt Schottelius, Chief Development Officer of MorphoSys AG.

"The activity observed with MOR208 in this difficult to treat population, particularly the durability and tolerability, position the program well for further development," said Bassil Dahiyat, President and CEO of Xencor. "Further, these data demonstrate the high anti-tumor activity that our cytotoxic XmAb® Fc domain creates in antibodies."

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 with an expansion to a total of 16 patients at the highest dose.

In total, 27 patients were enrolled, with a median age of 66 years. The patients were generally high risk: 14 patients had high-risk disease by the Rai staging system; 18 patients had chromosome abnormalities - 10 patients with del(17p13.1) and 8 with del(11q22.3); 24 patients had IgVH unmutated disease. All of these factors lead to a poor prognosis in clinical practice. Patients had a median of 4 prior therapies, with a range of 1 to up to 13.

MOR208 was generally well tolerated with no maximum-tolerated dose identified. The most common adverse events were infusion reactions, increased aspartate transaminase (AST), increased alanine aminotransferase (ALT), neutropenia, thrombocytopenia, fever, chills, and peripheral neuropathy. Infusion reactions occurred in 67% of patients, however, all were grade 1 or 2, and no reactions were seen following the first infusion.

On the basis of physical exam and laboratory studies, 18 patients (66.7%) achieved a partial response (PR), and the remaining 9 patients (33.3%) achieved stable disease (SD). Adding CT criteria, 8 patients (29.6%) achieved a PR with an additional 16 patients (59.3%) achieving SD. Two patients had progressive disease by CT criteria. Evaluating only the 16 patients at the 12 mg/kg dose level, which is the recommended phase 2 dose, 12 patients (75%) had a PR by physical exam criteria and 6 patients (37.5%) had a PR by CT criteria, two of these patients achieving the PR during the maintenance phase. Blood disease cleared in most patients, with a median reduction in absolute lymphocyte count from baseline of 90.8% and a decrease in CLL cell count. Median progression-free survival (PFS) for all patients was 199 days. For the 8 patients on the extended treatment cohort, PFS was 420 days.

"While not the primary endpoint of this trial, efficacy with this antibody is encouraging, with 67% of patients achieving a PR by clinical criteria and 30% using IWCLL 2008 criteria," commented Jennifer A. Woyach, Assistant Professor at the Ohio State University's Comprehensive Cancer Center and principle investigator of the trial. "These response rates are impressive for a single agent antibody and compare favorably with results for rituximab given on a weekly schedule as well as ofatumumab and

obinutuzumab in the relapsed setting."

A research paper presenting and discussing the results in CLL/SLL was recently published in the online issue of the peer-reviewed medical journal blood:
http://www.bloodjournal.org/content/early/2014/10/09/blood-2014-08-593269

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 80 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

About Xencor, Inc.
Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune diseases, asthma and allergic diseases, and cancer. Currently, eight candidates that have been engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's internally-discovered programs include: XmAb5871, in a Phase 1b/2a clinical trial for the treatment of rheumatoid arthritis and is in preparation for a clinical trial in IgG4-related disease; XmAb7195 in Phase 1a development for the treatment of asthma; and XmAb5574/MOR208 which has been licensed to Morphosys AG and is in Phase 2 clinical trials for the treatment of acute lymphoblastic leukemia and non-Hodgkin lymphoma. Xencor's XmAb antibody engineering technology enables small changes to the structure of monoclonal antibodies resulting in new mechanisms of therapeutic action. Xencor partners include Merck, Janssen R&D LLC, Alexion and Boehringer Ingelheim. For more information, please visit www.xencor.com.

This communication contains certain forward-looking statements concerning MOR208 (XmAb5874) and its therapeutic and commercial potential. The forward-looking statements contained herein represent the judgment of MorphoSys as of the date of this release and involve risks and uncertainties, including the risks and uncertainties of developing drugs that are safe and effective generally and the risks that the clinical trial results presented here may not be replicated in future clinical trial.. Should actual conditions differ from the Company's assumptions, actual results and actions may differ from those anticipated. MorphoSys and Xencor disclaim any intention or obligation to update any of these forward-looking statements.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/morphosys-and-xencor-publish-final-results-from-phase-12a-trial-of-mor208-xmab5574-in-cllsll-at-ash-annual-meeting-300005857.html

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