MorphoSys Presents Updated Clinical Data for Blood Cancer Candidate MOR208 in NHL and CLL at ASH 2016 Conference

MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) announced today the presentation of updated safety and efficacy data from two ongoing phase 2 clinical studies evaluating MOR208, an Fc-modified investigational antibody targeting CD19, in patients with advanced B-cell malignancies, at the 58th American Society of Hematology (ASH) Annual Meeting in San Diego, California/USA.

Continued long-lasting responses of more than 26 months reported in patients with relapsed/refractory NHL in a phase 2a trial with MOR208 monotherapy

An oral presentation reported data from a phase 2a study evaluating single-agent MOR208 in 92 patients with various subtypes of relapsed or refractory non-Hodgkin's lymphoma (NHL) including diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL) and other indolent NHL (iNHL). Results were consistent with prior updates from the study, reflecting in particular a continuation of long-lasting responses of more than 26 months.

“Patients with NHL, who are refractory or show relapse after previous anti-CD20-based therapies, have limited treatment alternatives and usually a very poor prognosis. These updated results illustrate our ongoing efforts to develop MOR208 as a potential new CD19-based antibody therapy for patients suffering from B-cell malignancies, including DLBCL, in phase 2 studies in combination with other cancer drugs,” said Dr. Arndt Schottelius, Chief Development Officer of MorphoSys AG.

At the last cutoff date, June 3, 2016, three patients with DLBCL and six with iNHL were in remission and on study treatment, with the longest responses in both subgroups ongoing for more than 26 months. Of these nine patients, seven showed complete responses and 2 experienced partial responses. The median duration of response was 20.1 months for DLBCL and not yet reached for iNHL. The overall response rate (ORR), based on complete responses (CR) and partial responses (PR), was 36% in the DLBCL subgroup and 33% in iNHL patients (both based on evaluable patients). Based on all patients with DLBCL and iNHL in the study, the ORR was 26% and 29%, respectively. The progression free survival (PFS) rate at 12 months was 39% in both subgroups. In addition to the patients with an objective response (PR or CR), the majority of patients with stable disease (SD) (5/6 DLBCL and 14/17 iNHL) had a reduction in target lesion size (central assessment).

PFS was similar in patients with rituximab non-refractory versus rituximab refractory tumors. Fifty-two patients (57%) in the study were classified as having rituximab refractory disease. Of those, five of 24 patients (21%) with DLBCL and five of 22 patients (23%) with iNHL responded to MOR208. Of the 10 responders with rituximab refractory disease, six had a response duration longer than 10 months, two of which lasted for more than 26 months.
The most common adverse events were infusion-related reactions (IRRs) occurring in 12% of the patients (11% of grade 1 or 2, 1% of grade 4) and neutropenia occurring in 12% of patients (3% of grade 1 or 2, 9% of grade 3 or higher). No treatment-related deaths were reported.

Number and title of the presentation
Abstract #623
Jurczak et al: Single-Agent MOR208 in Relapsed or Refractory (R-R) Non-Hodgkin’s Lymphoma (NHL): Results from Diffuse Large B-Cell Lymphoma (DLBCL) and Indolent NHL Subgroups of a Phase IIa Study

**Combination of MOR208 with lenalidomide and ibrutinib in CLL from phase 2 investigator-initiated trial**

A second presentation is a poster from investigators at The Ohio State University, who reported on an investigator-initiated trial (IIT) evaluating MOR208 in combination with lenalidomide in three cohorts of patients with chronic lymphatic leukemia (CLL): previously untreated CLL patients, relapsed/refractory CLL patients; and patients with Richter’s Transformation.

The trial also included a 4th cohort of ibrutinib-treated CLL patients with identified resistance mutations to ibrutinib in the tumors (molecular relapse) but no confirmed clinical relapse where MOR208 was added to ibrutinib therapy. Recent data have generally shown poor clinical outcomes in patients who relapse after a therapy with the BTK inhibitor ibrutinib and whose leukemia cells carry a mutation in the BTK gene prior to relapse.

According to the data presented, 34 patients have been enrolled in the study so far, 27 receiving MOR208 in combination with lenalidomide (11 of which in the previously untreated cohort, 11 in the relapsed/refractory cohort, 5 in the Richter’s Transformation cohort) and 7 receiving MOR208 plus ibrutinib, with patient accrual still ongoing.

Most frequent hematological adverse event over all cohorts were thrombocytopenia in 47% of patients (9% grade 3 or higher) and neutropenia in 35% (21% grade 3 or higher). There were no unexpected serious adverse events reported.

According to the abstract, in the group of CLL patients with ibrutinib-resistant cells receiving MOR208 in addition to ibrutinib, four out of seven patients have been on study for at least 3 cycles of 28 days each already, and no patient had developed progressive disease at the time of abstract data cut-off. Preliminary activity has been seen in all cohorts, including ibrutinib-resistant CLL patients.

“There is a high unmet medical need for CLL patients, especially those showing resistance to ibrutinib therapy,” said Dr. Jennifer Woyach, Assistant Professor of Internal Medicine at Ohio State University. “Therefore we added an additional cohort to our ongoing CLL study to evaluate MOR208 in combination with ibrutinib in order to investigate whether MOR208 could be a promising combination partner in this setting. We are looking forward to the continuation of the trial and to present further results going forward.”
Number and title of the presentation
Abstract #4386
Woyach et al: Updated Results from a Phase II Study of the Fc Engineered CD19 Antibody MOR208 in Combination with Lenalidomide for Patients with Chronic Lymphocytic Leukemia (CLL) and Richter’s Transformation or Ibrutinib for Patients with Ibrutinib-Resistant Clones

MorphoSys held an Investor & Analyst Event at the 2016 ASH Annual Meeting on December 5, 2016, at 8:00pm PST (December 6, 2016: 4:00am GMT, 5:00am CET). Two clinical investigators presented clinical data for MorphoSys’s investigational agents MOR208 and MOR202.

A replay and the presentation will be made available at http://www.morphosys.com.

Webcast: https://www.webcaster4.com/Webcast/Page/359/18722

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.

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