



Press Release

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MorphoSys Starts Phase 2 Trial of MOR208 in Combination with Idelalisib in Patients with Relapsed or Refractory CLL or SLL Previously Treated with a BTK Inhibitor

MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) announced today that the first patient was dosed in a Phase 2 combination trial of MOR208 with idelalisib (Zydelig®). The trial, which has been named **COSMOS** (CLL patients assessed for **ORR & Safety in MOR208 Study**), is designed to evaluate the safety and efficacy of MOR208 in combination with the PI3K delta inhibitor idelalisib in adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Patient enrolled must have been refractory or shown relapse or intolerance to a prior, most recent, therapy with a Bruton's Tyrosine Kinase (BTK) inhibitor (e.g. ibrutinib). MOR208 is an investigational Fc-engineered monoclonal antibody targeting CD19 that is being developed for the treatment of patients with B cell malignancies. CLL is the most common type of leukemia in Western populations.

"We are pleased to kick off the COSMOS trial. This is the third in a series of clinical studies we have initiated this year investigating combination therapies with our CD19 antibody MOR208 in hemato-oncological indications", commented Dr. Arndt Schottelius, Chief Development Officer of MorphoSys AG. "There is a particularly high medical need for chronic lymphocytic leukemia (CLL) patients, especially following discontinuation of a BTK inhibitor therapy. We look forward to exploring the potential of MOR208 in this indication in combination with idelalisib. In addition, we are also planning to investigate MOR208 with a second combination partner in this patient population and will provide more details soon."

The single-arm, open-label, multicenter COSMOS study will enroll patients in Europe and in the USA. Patients will receive intravenous infusions of MOR208 for up to 24 cycles of 28 days each. Idelalisib is taken orally, 150 mg twice-daily for the study duration. The study will include a safety run-in phase consisting of a safety evaluation by an independent data monitoring committee (IDMC).

The study's primary endpoint is overall response rate (ORR), comprising complete responses (CR) and partial responses (PR). Secondary outcome measures include progression-free survival (PFS), overall survival (OS) and duration of response (DoR), as well as an evaluation of the drug combination's safety and pharmacokinetic parameters of MOR208.

Detailed information on the trial can be found on 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-engineered ("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 is currently investigating MOR208 as an immunotherapeutic treatment option in several phase 2 combination studies in patients with B cell malignancies. A phase 2 study named L-MIND (Lenalidomide-MOR208 IN DLBCL) is investigating the safety and efficacy of MOR208 in combination with lenalidomide in patients with relapsed or refractory DLBCL. A phase 2/3 study named B-MIND (Bendamustine-MOR208 IN DLBCL) is evaluating the safety and efficacy of MOR208 in combination with the chemotherapeutic agent bendamustine in comparison to rituximab plus bendamustine in patients with relapsed or refractory DLBCL. The B-MIND trial, which is currently in the safety part, is planned to be transitioned into a pivotal phase 3 part in 2017. A third trial named COSMOS (CLL patients assessed for ORR & Safety in MOR208 Study) is investigating safety and efficacy of MOR208 together with idelalisib in patients with relapsed or refractory CLL or SLL after discontinuation of BTK inhibitor therapy.

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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