



## Media Release

Planegg/Munich, Germany, December 11, 2017

### **MorphoSys Presents Clinical Data on MOR208 plus Lenalidomide in Aggressive Lymphoma (R/R DLBCL) at ASH 2017 Conference**

- Preliminary median progression-free survival of 11.3 months
- Objective response rate (ORR) of 52%, complete remission rate (CR) of 32%
- No unexpected toxicities observed; no infusion-related reactions reported for MOR208
- MOR208 plus lenalidomide recently received FDA Breakthrough Therapy designation for non-transplant eligible patients with R/R DLBCL

MorphoSys AG (FSE: MOR; Prime Standard Segment; TecDAX, OTC: MPSYY) today presented clinical data from the ongoing phase 2 clinical trial (L-MIND) evaluating MOR208 in combination with lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL). DLBCL is the most frequent type of malignant lymphoma worldwide and accounts for approximately 30% of all non-Hodgkin lymphomas. Data will be reported in a [poster presentation \(available for download\)](#) at the 59<sup>th</sup> American Society of Hematology (ASH) Annual Meeting in Atlanta, Georgia/USA. MOR208 is an investigational Fc-engineered monoclonal antibody directed against CD19.

The data presented at ASH formed the basis for the Breakthrough Therapy designation recently awarded by the FDA for MOR208, in combination with lenalidomide, for the treatment of non-transplant eligible patients with R/R DLBCL.

At data cut-off (June 13, 2017), 51 patients had been enrolled in the study, of whom 44 were evaluable for efficacy assessments. Preliminary data show an objective response in 23 out of 44 patients (ORR: 52%), 19 (83%) of whom show ongoing responses. Complete remission was seen in 14 out of 44 patients (CR: 32%). The median time to response was 1.8 months, the median time to complete response was 2.3 months. The preliminary median progression-free survival (PFS) based on Kaplan Meier calculation was 11.3 months.

No unexpected toxicities were observed for the treatment combination and no infusion-related reactions were reported for MOR208. The most frequent adverse events with a toxicity grading of 3 or higher were neutropenia, thrombocytopenia, and leukopenia, observed in 35%, 10%, and 8% of patients, respectively. Pneumonia and hypokalemia were reported for 10% and 8% of the patients. To date, 45% of patients required a reduction of their lenalidomide dose, from a starting dose of 25mg daily.

The trial has recently completed patient recruitment as required by the study protocol. To date, 81 patients have been enrolled.

“We are very encouraged by the updated clinical trial results from the ongoing L-MIND trial, especially the complete responses and the duration of responses we have seen so far. DLBCL is a very aggressive lymphoma. In particular, those patients with relapsed or refractory DLBCL who are not eligible for high-dose chemotherapy and autologous stem cell transplantation are in need of more therapeutic options. Based on the FDA Breakthrough Therapy designation we recently

obtained, we intend to develop MOR208 together with lenalidomide as a potential new treatment option for this patient group as quickly as possible,” commented Dr. Malte Peters, Chief Development Officer of MorphoSys AG.

The L-MIND trial (Lenalidomide plus MOR208 in DLBCL) is a single-arm, open-label, multicenter study of MOR208 in combination with lenalidomide. The trial is enrolling patients with relapsed or refractory DLBCL after up to three prior lines of therapy, with at least one prior therapy including an anti-CD20 targeting therapy (e.g. rituximab). Patients could not be candidates for high-dose chemotherapy and autologous stem cell transplantation. Patients enrolled had a median age of 74 years.

#### **Details of the MOR208 presentation at ASH 2017:**

Abstract #4123; Poster III

[Single-Arm Phase II Study of MOR208 Combined with Lenalidomide in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma: L-Mind](#)

The poster will be presented during the session #626 “Aggressive Lymphoma (Diffuse Large B-Cell and Other Aggressive B-Cell Non-Hodgkin Lymphomas)—Results from Prospective Clinical Trials” on Monday, December 11, 2017, 6:00pm-8:00pm EST (Dec. 12, 2017, 0:00am-2:00am CET), in the Georgia World Congress Center, Bldg A, Lvl 1, Hall A2.

In addition to the presentation, the abstract has been published online in the December 8, 2017 supplemental volume of Blood. Additional information can be found at [www.hematology.org](http://www.hematology.org), including the abstract.

MorphoSys will hold an investor & analyst conference call after the 59th American Society of Hematology (ASH) Annual Meeting 2017 on December 12, 2017, 11:00am EST(5:00pm CET).

Dial in:

**Germany: +49 89 2444 32975**

**United Kingdom: +44 20 3003 2666**

**USA: +1 202 204 1514**

The presentation slides and webcast link will be available at [www.morphosys.com/conference-calls](http://www.morphosys.com/conference-calls). A slide-synchronized audio replay of the conference will also be available at the corporate website following the live event.

#### 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<sup>®</sup>5574) is an investigational Fc-enhanced monoclonal antibody directed against CD19, a prominent marker present on the surface of B-cells. 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 comparison to the combination of the anti-CD20 antibody rituximab plus bendamustine in patients with relapsed/refractory DLBCL who are not eligible for high-dose chemotherapy (HDC) and autologous stem cell transplantation (ASCT). Furthermore, MOR208 is currently being clinically investigated in combination with idelalisib or venetoclax in patients with relapsed/refractory CLL after discontinuation of a prior Bruton tyrosine kinase (BTK) inhibitor therapy (e.g. ibrutinib).

#### 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 pipeline of more than 100 programs in R&D, around a quarter of which are 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 in 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>.

HuCAL<sup>®</sup>, HuCAL GOLD<sup>®</sup>, HuCAL PLATINUM<sup>®</sup>, CysDisplay<sup>®</sup>, RapMAT<sup>®</sup>, arYla<sup>®</sup>, Ylanthia<sup>®</sup>, 100 billion high potentials<sup>®</sup>, Slonomics<sup>®</sup>, Lanthio Pharma<sup>®</sup> and LanthioPep<sup>®</sup> are registered trademarks of the MorphoSys Group.

*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:**

##### **MorphoSys AG**

Anke Linnartz

Head of Corporate Communications & IR

Jochen Orłowski

Associate Director Corporate Communications & IR

Alexandra Goller

Senior Manager Corporate Communications & IR

**Tel: +49 (0) 89 / 899 27-404**

**[investors@morphosys.com](mailto:investors@morphosys.com)**