



## Press Release

Martinsried/Munich, November 9, 2009

# **MorphoSys Receives Regulatory Approval to Start Phase 1b/2a Clinical Trial for MOR103 Program**

## **Germany's Paul-Ehrlich-Institute Approves Clinical Trial in Rheumatoid Arthritis Patients**

MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX) announced today that it has received clearance from Germany's Paul-Ehrlich-Institute as well as a positive opinion from the ethics committees in Germany to commence a Phase 1b/2a human clinical trial in patients with rheumatoid arthritis (RA) of its lead drug MOR103, a fully human monoclonal antibody directed against **Granulocyte Macrophage-Colony Stimulating Factor (GM-CSF)**. In total, the randomized, double-blind, placebo-controlled, dose-escalation trial is expected to enroll 135 patients and will be conducted in multiple centers in several European countries. Patients with active RA despite previous therapy with NSAIDs, corticosteroids, DMARDs and/or anti-TNF-alpha will each receive four infusions of either the HuCAL-derived antibody MOR103 or placebo in three ascending dose cohorts. Enrollment is expected to be completed in the first half of 2011. The final results of the trial are expected in H1 2012.

The primary endpoint of the trial is to determine the safety and tolerability of multiple doses of up to 1.5 mg/kg of MOR103 in patients with active RA. Secondary outcome measures will evaluate pharmacokinetics, immunogenicity, and the drug's potential to improve clinical signs and symptoms of RA as measured by ACR and EULAR28 response criteria and patient reported outcomes.

"We are pleased to have achieved clearance by the regulatory authorities and ethics committees in Germany in such a short time frame which speaks for the high quality of the application documents provided by MorphoSys," commented Dr. Arndt Schottelius, Chief Development Officer. "We'll continue to work towards finalization of the entire approval process in all European countries where we have filed."

### About MorphoSys:

MorphoSys is an independent biotechnology company that develops novel antibodies for therapeutic, diagnostic and research applications. The Company's HuCAL technology is one of the most powerful methods available for generating fully human antibodies. By successfully applying this and other proprietary technologies, MorphoSys has become a leader in the field of therapeutic antibodies, one of the fastest-growing drug classes in human health-care. Through its alliances with some of the world's leading pharmaceutical companies, MorphoSys has created a pipeline of more than 60 drug candidates. The Company is expanding its drug pipeline by adding new partnered programs, and by building a portfolio of fully-owned therapeutic antibodies. For its proprietary portfolio, the Company is focused on the areas of oncology and inflammation, within which it plans to have eight active programs by the end of 2009. Its most advanced program is MOR103, a first-in-class, fully human antibody against GM-CSF. MorphoSys expects to commence a Phase Ib/IIa trial of this antibody in rheumatoid arthritis patients in the second half of 2009. Via its business unit AbD Serotec, MorphoSys is expanding the reach of its

technologies in the diagnostics and research markets. MorphoSys is headquartered in Munich, Germany and listed on the Frankfurt Stock Exchange under the symbol "MOR". For further information, visit <http://www.morphosys.com/>

HuCAL<sup>®</sup>, HuCAL GOLD<sup>®</sup>, HuCAL PLATINUM<sup>®</sup>, CysDisplay<sup>®</sup> and RapMAT<sup>®</sup> are registered trademarks of MorphoSys AG.

*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:**

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

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

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