



# Media Release:

Gaithersburg, MD, USA and Martinsried/Munich, Germany, 9 March 2015

# Emergent BioSolutions and MorphoSys Initiate Phase 1 Clinical Study to Evaluate the Novel Oncology Immunotherapeutic MOR209/ES414 for Prostate Cancer

Emergent BioSolutions Inc. (NYSE: EBS) and MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX, OTC: MPSYY) today announced the initiation of a Phase 1 clinical study to evaluate the safety, tolerability, and clinical activity of MOR209/ES414 in patients with metastatic castration-resistant prostate cancer (mCRPC). Under the terms of the companies' co-development and commercialization agreement, achievement of this milestone triggers a payment of US \$5 million by MorphoSys to Emergent.

MOR209/ES414 is an immunotherapeutic protein developed by Emergent using its proprietary ADAPTIR<sup>™</sup> (modular protein technology) platform. Preclinical *in vitro* and *in vivo* studies have shown MOR209/ES414 redirects T-cell cytotoxicity towards cells expressing Prostate Specific Membrane Antigen (PSMA), an antigen commonly found on prostate cancer cells.

Barry Labinger, Executive Vice President and President Biosciences Division at Emergent BioSolutions said, "Emergent is pleased to announce the dosing of our first patient in this Phase 1 clinical study. Prostate cancer is the most common cancer in men, and there is a significant need for improved treatment options. We believe that the immunotherapeutic approach represented by MOR209/ES414 offers the promise of meaningfully improved outcomes for patients with mCRPC. We are excited to work with our partner MorphoSys to evaluate the potential of MOR209/ES414 in the clinic."

Arndt Schottelius, Chief Development Officer of MorphoSys, added, "MOR209/ES414 has the potential to address a clear unmet medical need in prostate cancer. We are thus delighted to see this compound moving into the clinic as expected in early 2015. This is the fourth clinical candidate in our growing proprietary portfolio of compounds and increases the total number of clinical programs in our pipeline to 23."

The study will be conducted in two stages. The primary objective of Stage 1 is to identify the maximum tolerated dose (MTD) of MOR209/ES414 administered intravenously, with weekly dosing for three months and bi-weekly thereafter, to patients with mCRPC. The secondary objectives are to evaluate the tolerability, pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity, cytokine response, and clinical activity of MOR209/ES414. Within Stage 2, the primary objective is to evaluate clinical activity in patients that have or have not received prior chemotherapy, while secondary objectives are to further characterize the safety profile, PK, PD, and immunogenicity of MOR209/ES414.

This open-label Phase 1 clinical study will be conducted in the U.S. and Australia, with a planned enrollment of up to 130 patients. More information can be found on <u>clinicaltrials.gov</u>.

## About MOR209/ES414

MOR209/ES414 is a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against cells expressing Prostate Specific Membrane Antigen (PSMA), an antigen commonly overexpressed on prostate cancer cells. The MOR209/ES414 molecule was constructed using Emergent's ADAPTIR technology platform and selectively binds to the T cell receptor on cytotoxic T cells and PSMA on tumor cells. MOR209/ES414 contains





two pairs of binding domains, each targeting a unique antigen, linked to opposite ends of an immunoglobulin Fc domain to extend the half-life and enable use of a purification process typical of Ig-based molecules. In preclinical studies, MOR209/ES414 has been shown to redirect T-cell cytotoxicity towards prostate cancer cells expressing PSMA.

### About the ADAPTIR<sup>™</sup> Platform

ADAPTIR bispecific proteins are modular, single chain polypeptides that comprise two separate binding domains, a hinge segment, and an effector domain (huFc). They have a differentiated structure from monoclonal antibodies and can generate a unique signaling response. Some ADAPTIR molecules, like MOR209/ES414, may mediate T-cell cytotoxicity by redirecting T cells against tumor cells. In addition, monospecific ADAPTIR proteins may mediate complement dependent cytotoxicity and Fc dependent cytotoxicity, similar to monoclonal antibodies.

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#### **About Prostate Cancer**

Prostate cancer is the most common cancer in men with approximately 230,000 new cases annually in the United States or 900,000 new cases annually worldwide. Screening, radiation, surgery and hormone ablation therapy have greatly improved the detection and treatment of early stage prostate cancer. However, the new therapies only improve life expectancy by a few months for patients with metastatic castration-resistant prostate cancer.

#### **About Emergent BioSolutions**

Emergent BioSolutions is a global specialty biopharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. Additional information about us may be found at <u>www.emergentbiosolutions.com</u>. Follow us on twitter: <u>@emergentbiosolu</u>.

#### 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 <u>pipeline</u> of more than 90 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 <u>http://www.morphosys.com</u>.

HuCAL<sup>®</sup>, HuCAL GOLD<sup>®</sup>, HuCAL PLATINUM<sup>®</sup>, CysDisplay<sup>®</sup>, RapMAT<sup>®</sup>, *arYla*<sup>®</sup>, Ylanthia<sup>®</sup> and 100 billion high potentials<sup>®</sup> are registered trademarks of MorphoSys AG.

Slonomics<sup>®</sup> is a registered trademark of Sloning BioTechnology GmbH, a subsidiary of MorphoSys AG.





#### **Emergent BioSolutions Safe Harbor Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, are forward-looking statements. Forward-looking statements in this press release include statements about the potential and therapeutic opportunity of the MOR209/ES414 molecule and potential milestone and royalty payments for development, regulatory approval and sales of the product candidate. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including the success of clinical trials for MOR209/ES414; the timing of and our ability to obtain and maintain regulatory approvals for MOR209/ES414; the rate and degree of market acceptance and clinical utility of MOR209/ES414 as a product; and our commercialization, marketing and manufacturing capabilities and strategy with respect to MOR209/ES414. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

#### MorphoSys Safe Harbor Statement

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.

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