



# Media Release:

Rockville, MD, USA and Martinsried/Munich, Germany, 19 August 2014

# **Emergent BioSolutions and MorphoSys Sign License Agreement to Co-Develop and Commercialize Prostate Cancer Drug Candidate ES414**

Emergent BioSolutions Inc. (NYSE: EBS) and MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX, OTC: MPSYY) today announced an agreement for the joint development and commercialization of Emergent's preclinical bi-specific antibody, ES414, targeting prostate cancer. Under the terms of the agreement, Emergent will receive an upfront payment of US\$20 million and milestone payments of up to US\$163 million. These milestone payments are linked to specific events, including successful development of ES414 in several indications and securing approval in certain territories. Emergent and MorphoSys will jointly develop ES414, with MorphoSys bearing 64% and Emergent 36% of the total costs. Emergent will retain commercialization rights in the U.S. and Canada, with a tiered royalty obligation to MorphoSys, from mid-single digit up to 20%. MorphoSys will gain worldwide commercialization rights excluding the U.S. and Canada, with a low single digit royalty obligation to Emergent. Emergent will manufacture and supply clinical material from its manufacturing facilities in Baltimore, Maryland. Additional financial details were not disclosed.

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

Barry Labinger, Executive Vice President and President Biosciences Division at Emergent BioSolutions, stated: "Emergent looks forward to collaborating with MorphoSys to potentially address important unmet needs amongst patients suffering from prostate cancer. Our companies bring complementary capabilities, compatible cultures and values, and a shared commitment to the highest quality development and commercialization of ES414. We expect to begin clinical development within the next six months. Progress with ES414 will help validate our ADAPTIR platform, which we believe has broad potential to generate additional novel treatments for cancer and other important diseases. We are encouraged by our partnership with MorphoSys and the continued interest of multiple parties in our ADAPTIR platform."

Arndt Schottelius, Chief Development Officer of MorphoSys, added: "We are pleased to be working with Emergent BioSolutions. We believe ES414 has the potential to be an important therapy for prostate cancer, where there is a pressing need for better treatments. The preclinical data suggest that the molecule has a number of potential advantages over other drug candidates in this indication. Our goal is to combine our capabilities with those of Emergent to enable the fastest possible development and commercialization of ES414."

Emergent and MorphoSys plan to initiate a Phase 1 clinical trial evaluating ES414 in patients with metastatic castration-resistant prostate cancer (mCRPC) within the next six months. The initial phase of the trial will be conducted in the U.S. and Australia, with Emergent as the sponsor.

#### About ES414

ES414 is a targeted immunotherapeutic protein, which activates host T-cell immunity specifically against prostate cancer cells expressing Prostate Specific Membrane Antigen (PSMA), an antigen commonly overexpressed on prostate cancer cells. The 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. 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, ES414 has been shown to redirect Tcell 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 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 80 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>.

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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 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 ES414; the timing of and our ability to obtain and maintain regulatory approvals for ES414; the rate and degree of market acceptance and clinical utility of ES414 as a product; and our commercialization, marketing and manufacturing capabilities and strategy with respect to 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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