



EMERGENT BIOSOLUTIONS AND VALNEVA INITIATE PHASE 1 CLINICAL STUDY TO EVALUATE VACCINE CANDIDATE AGAINST ZIKA VIRUS

GAITHERSBURG, Md. and LYON, France, February 26, 2018 - Emergent BioSolutions Inc. (NYSE: EBS) and Valneva SE (VLA) today announced the initiation of a Phase 1 clinical trial in the U.S. to evaluate the safety and immunogenicity of VLA1601, their vaccine candidate against Zika virus.

The Phase 1 clinical trial is a randomized, observer-blinded, placebo-controlled, single center study. This study, in approximately 65 healthy adults, will investigate two dose levels of VLA1601 when administered using two different vaccination schedules. Initial data from the trial are expected to be available in late 2018 or early 2019.

Adam Havey, Executive Vice President of Business Operations at Emergent BioSolutions, said, "Emergent's commitment to our mission – to protect and enhance life – fuels our pursuit for preparedness solutions against Zika virus, the consequences of which remain a public health challenge that requires attention. Our collaboration with Valneva on this Phase 1 study intends to make meaningful contributions to global research in this field."

Thomas Lingelbach, President & CEO of Valneva, added, "We are delighted that our collaboration with Emergent has resulted in the clinical progression of a very promising vaccine candidate. This vaccine candidate has already demonstrated an excellent preclinical profile comparable to Valneva's licensed Japanese Encephalitis vaccine."

Under the terms of the agreement signed in July 2017, the parties will share all costs until the availability of Phase 1 data in the U.S. Valneva will be responsible for the program's execution until completion of the Phase 1 trial through a joint governance structure.

Upon availability of Phase 1 data, Emergent will have the option to continue the development and commercialization of a Zika vaccine under its worldwide exclusive license agreement with Valneva for a milestone payment of €5 million. The agreement provides Valneva potential additional milestone payments of up to €44 million related to product development, approval, commercialization, and product sales, future royalties on annual net sales, and the right, prior to a Phase 3 clinical trial, to negotiate with Emergent exclusive commercialization rights in Europe.

The companies are expected to enter into a technology transfer agreement at a later time to enable transfer of Valneva's technology to Emergent's Bayview manufacturing facility in Baltimore, Maryland.

About Zika Virus

The Zika virus (ZIKV) is a mosquito-borne flavivirus that was first discovered in 1947. The first human cases were detected in 1952. Since then, outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, in 2015, in the Americas.

According to the World Health Organization, there is scientific consensus that ZIKV is a cause of microcephaly and Guillain-Barré syndrome. Since 2013, 31 countries and territories have reported cases of microcephaly and other central nervous system malformations associated with ZIKV infection.





About VLA1601

VLA1601 is a highly purified inactivated vaccine candidate against the Zika virus, developed using the same manufacturing platform as Valneva's IXIARO® (JESPECT®) Japanese Encephalitis ("JE") vaccine. Certain health authorities and key opinion leaders have expressed a preference for the purified inactivated vaccine approach over other vaccine technologies (such as live-attenuated approaches) since the initial target population for a Zika vaccine is expected to be women of child-bearing age, including those who may be pregnant. There is a theoretical risk that live-attenuated or replication competent viral vaccines given to pregnant women may be capable of crossing the placenta and infecting the fetus. For this reason, live vaccines are not recommended during pregnancy. In preclinical development, VLA1601 demonstrated excellent purity and had an overall biological, chemical and physical profile comparable to the commercially produced JE vaccine, which means that a similar safety and immunogenicity profile could be expected. Valneva has an established manufacturing process in its dedicated clinical JE vaccine facility.

About Emergent BioSolutions

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, intentional, and naturally occurring public health threats. Through our work, we envision protecting and enhancing 50 million lives with our products by 2025. Additional information about the company may be found at emergentbiosolutions.com. Follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

About Valneva SE

Valneva is a fully integrated, commercial stage biotech company focused on developing innovative life-saving vaccines. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has proprietary vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 450 employees. More information is available at www.valneva.com.

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Emergent 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. 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 the planned development program; the timing of and ability to obtain and maintain regulatory approvals for the product candidate; and our commercialization, marketing and manufacturing capabilities. 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.

Valneva Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of the future. In some cases, you can identify forwardlooking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or





implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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