



EMERGENT BIOSOLUTIONS AND VALNEVA REPORT POSITIVE PHASE 1 RESULTS FOR THEIR VACCINE CANDIDATE AGAINST THE ZIKA VIRUS

GAITHERSBURG, Md. and Saint-Herblain, France, November 19, 2018 - Emergent BioSolutions Inc. (NYSE: EBS) and Valneva SE (VLA) today announced positive interim results for the Phase 1 study evaluating VLA1601, their vaccine candidate against the Zika virus.

The highly purified inactivated vaccine candidate, VLA1601, met the study's primary endpoint showing a favorable safety profile in all doses and schedules tested.

VLA1601 was also immunogenic in all treatment groups and induced both dose- and schedule-dependent neutralizing antibodies against the Zika virus with the kinetics expected for an inactivated, alum-adjuvanted whole-virus vaccine. Seroconversion Rates (SCR) reached up to 85.7% on Day 35 (Interim Analysis of Data up to Day 56).

The Phase 1 study was designed to assess safety and immunogenicity. It is being co-financed by Emergent and Valneva as part of an exclusive, worldwide license agreement signed in July 2017. The agreement includes pre-defined post-Phase 1 opt-in rights for Emergent.

Wolfgang Bender, MD, PhD, chief medical officer of Valneva commented, "We are pleased to see progress of this promising vaccine candidate for the prevention of infections caused by the Zika virus and their serious implications during pregnancy. The excellent safety profile supports further optimization of the elicited immune response to cover an unmet medical need in the most vulnerable populations."

Kelly Lyn Warfield, PhD, vice president, Vaccines and Anti-Infectives Research and Development at Emergent BioSolutions, added, "Emergent's continued focus on the development of prevention and treatment strategies for emerging infectious diseases is part of its broader mission – to protect and enhance life. Through our work, we are committed to making a positive impact on public health across the globe."

About the Phase 1 Clinical Study VLA1601-101

VLA1601-101 is a first-in-human, randomized, placebo-controlled and observer-blinded study. It is assessing the safety and immunogenicity of two different dose levels of the alum adjuvanted, inactivated whole virus Zika vaccine candidate VLA1601 in 67 healthy, flavivirus-naïve adults aged 18-49 years. The study is being conducted in Knoxville, TN, U.S.

Participants received two vaccinations with a lower (3AU) or higher dose (6AU) – either 7 or 28 days apart.

The current analysis includes full, final data for all analyses (safety and immunogenicity) up to day 56 after the first vaccination.

The final analysis at day 208 after first vaccination, which is expected in the first quarter 2019, will include additional immunogenicity data such as Geometric Mean Titres (GMTs), rate of subjects with seroconversion and fold-increase of ZIKA virus specific neutralizing antibodies titres as compared to base-line, measured by PRNT.

Additional information, including a detailed description of the study design and eligibility criteria is available at ClinicalTrials.gov using identifier NCT03425149.

About Zika Virus

The Zika virus 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. In pre-clinical development, VLA1601 demonstrated excellent purity and had an overall biological, chemical and physical profile comparable to the commercially produced JE vaccine. Valneva has an established manufacturing process in its dedicated clinical JE vaccine facility.

About the exclusive worldwide license for Valneva's Zika vaccine technology

On July 26, 2017 Emergent and Valneva announced the execution of an exclusive worldwide license agreement for Valneva's Zika vaccine technology. Under the terms of the agreement, the parties share all costs until the availability of final Phase 1 data in the U.S. Valneva is responsible for the program's execution until completion of the Phase 1 trial through a joint governance structure. Upon availability of final Phase 1 data, Emergent will have the option to continue the development and commercialization of a Zika vaccine 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 for exclusive commercialization rights in Europe. As part of any further development, 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 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. We aspire to be a Fortune 500 company recognized for protecting and enhancing life, driving innovation, and living our values. Additional information about the company may be found at www.emergentbiosolutions.com. Find us on LinkedIn and 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 forward-looking 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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