

**VALNEVA SE**

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## Valneva and Emergent BioSolutions Join Forces to Develop a Vaccine against the Zika Virus

- Valneva grants Emergent an exclusive worldwide license for its Zika vaccine technology (ZIKV)
- Valneva and Emergent will co-develop the vaccine until the release of Phase I data with operational responsibility for Valneva
- Emergent has an option to continue product development upon the release of Phase I data, in exchange for an initial €5 million milestone payment, potential additional milestones of up to €44 million related to product development, approval, commercialization, and product sales, and royalties on annual net sales
- Agreement includes a technology transfer to Emergent's Bayview manufacturing facility for Phase II/III production and future commercial supplies
- Parties seek to commence Phase I in the US in late 2017 or early 2018 and anticipate first Phase I data within six months after trial initiation

Lyon (France), July 26, 2017 - Valneva SE (VLA), a fully integrated, commercial stage biotech company focused on developing innovative, life-saving vaccines, announces today that it has granted Emergent BioSolutions Inc. (NYSE:EBS) exclusive worldwide rights to its Zika vaccine technology ZIKV. Valneva and Emergent will co-develop ZIKV-VLA1601, a highly purified inactivated vaccine candidate against the Zika virus, which was successfully developed by Valneva using the established inactivated manufacturing platform of its licensed Japanese Encephalitis vaccine IXIARO®/ JESPECT®.

Emergent and Valneva seek to initiate a Phase I clinical trial in the U.S. in late 2017 or early 2018 and anticipate Phase I data within six months after trial initiation.

**Franck Grimaud, President & Chief Business Officer (CBO) of Valneva**, commented *"We are extremely proud that Emergent recognizes the value of our vaccine platform technology, our Zika product candidate and our competencies in the field. We look forward to working jointly towards being among the first companies in the world to generate a Zika vaccine."*

Under the terms of the agreement, Emergent receives an exclusive worldwide license for Valneva's Zika vaccine technology. The parties will share all costs until the availability of Phase I data in the US. Valneva will be responsible for the program's execution until completion of the Phase I trial through a joined governance structure.



Upon availability of Phase I data, Emergent has an opt-in right at predefined terms and conditions, including an opt-in milestone payment of €5 million, in addition to a €1 million upfront payment paid on signing, potential additional milestone payments of up to €44 million related to product development, approval, commercialization, and product sales, and future royalties on annual net sales.

The agreement also includes a technology transfer to Emergent's Bayview manufacturing facility in Baltimore, Maryland in the US for Phase II/III and any future commercial manufacturing. Valneva retains a right of first negotiation for potential product commercialization in Europe.

#### **About Valneva's Zika vaccine candidate (ZIKV) - VLA1601**

VLA1601 is a highly Purified Inactivated Vaccine ("PIV") candidate against the Zika virus, developed using the same manufacturing platform as Valneva's IXIARO<sup>®</sup> (JESPECT<sup>®</sup>) Japanese Encephalitis ("JE") vaccine. Health authorities and Key Opinion Leaders have expressed a preference for the PIV 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 pre-clinical 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 IXIARO<sup>®</sup>/JESPECT<sup>®</sup>**

Valneva's Japanese encephalitis vaccine is indicated for active immunization for the prevention of Japanese encephalitis in persons who travel to or live in endemic areas. IXIARO<sup>®</sup> is the only vaccine against Japanese encephalitis being marketed to the US military as well as travelers from North America or Europe visiting endemic countries.

IXIARO<sup>®</sup> is approved for use in individuals aged 2 months and older in the US, EU, Norway, Liechtenstein and Iceland. In Canada, Hong Kong, Singapore, Israel and Switzerland, IXIARO<sup>®</sup> is indicated for use in persons 18 years of age and above. In Australia and New Zealand, the Japanese encephalitis vaccine is marketed under the trade name JESPECT<sup>®</sup> and is indicated for use in persons 18 years of age and above. In Europe, a rapid immunization schedule (two doses in one week) is approved for IXIARO<sup>®</sup> in adults aged 18 ≤ 65 years.

## **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<sup>®</sup>/JESPECT<sup>®</sup> indicated for the prevention of Japanese encephalitis and DUKORAL<sup>®</sup> indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has proprietary vaccines in development including candidates against *Clostridium difficile* and Lyme disease. A variety of partnerships with leading pharmaceutical companies complement the Company's value proposition and include vaccines being developed using Valneva's innovative and validated technology platforms (EB66<sup>®</sup> vaccine production cell line and IC31<sup>®</sup> adjuvant).

Valneva shares are tradable on Euronext-Paris, the Vienna stock exchange and Deutsche Börse's electronic platform Xetra<sup>®</sup>. The Company has operations in France, Austria, Great Britain, Sweden, Canada and the US with over 400 employees. More information is available at [www.valneva.com](http://www.valneva.com).

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## **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.