Valneva SE (VLA.PA)

Valneva Licenses Zika Vaccine Technology to Emergent BioSolutions

Valneva (Euronext Paris: VLA.PA) announced yesterday that it has granted an exclusive worldwide license to Emergent BioSolutions (NYSE: EBS) for its Zika vaccine technology. Under the terms of the agreement, Valneva will receive an upfront payment of €1 million, and the two companies will co-develop the Zika vaccine candidate, VLA1601, until Phase I data. Afterwards, Emergent has the option to continue development of the vaccine in exchange for a €5 million payment, plus up to €44 million in potential milestones related to product development, commercialization, and product sales, and a royalty on annual net sales. A Phase I study in the US is expected to begin in late 2017 or early 2018, with data coming within 6 months of the trial starting.

- **Valneva Establishes Collaboration Partner for Zika Vaccine Development.** Under the terms of the agreement, Valneva will receive an upfront payment of €1 million, and it will co-develop and share all costs related to VLA1601 with Emergent BioSolutions until Phase I data. Following this, Emergent has the option to continue product development in exchange of a €5 million milestone payment, up to €44 million in milestones related to product development, commercialization, and product sales, and a royalty on annual net sales. The agreement also includes a potential technology transfer to Emergent's manufacturing facility for Phase II/III and commercial production. If approved, Valneva has the right of first negotiation for commercialization in Europe.

- **Valneva May Have a Competitive Advantage in Developing a Zika Vaccine.** Valneva may have a competitive advantage in developing a Zika vaccine, since the Zika virus is related to the Japanese encephalitis virus (JEV), for which the Company has developed and markets the Ixiaro/Jespect vaccine. Notably, VLA1601 is a highly purified inactivated vaccine (PIV) against the virus, which the WHO has expressed a preference for. Previously, the company announced that VLA1601 has shown encouraging results in mice. The WHO declared a global public health emergency in early 2016 against Zika, and it is estimated that up to 4 million people in the Americas contracted the virus in 2016. The virus causes a range of birth defects, including microcephaly, possibly through the depletion of neural progenitor cells in the developing fetus.

### Expected Upcoming Milestones

- H2 2017 – Potential partnership agreement for VLA84 development program.
- H2 2017 – Potentially begin a Phase I study with Chikungunya candidate.
- Late 2017- early 2018 – Initiation of a Phase I study with VLA1601 for Zika.
- Mid 2018 – Phase I data with VLA1601 for Zika.
- Q1 2018 – Begin Phase II study with VLA15 for Lyme disease.
Zika Vaccines May have an Accelerated Development Pathway. Because of the immediate need for protection against the Zika virus, a vaccine showing early signs of efficacy with a clean safety profile could be considered for accelerated development. Valneva’s management team has previously referred to a meningococcal epidemic in New Zealand, where development-stage meningococcal B vaccines that were determined to be safe and showed promising signs of efficacy were advanced from early-stage trials into the field for a large-scale Phase III trial. Although a similar situation could occur in the US, the FDA has made no announcements yet regarding the regulatory pathway for potential Zika vaccines.

Risk to Investment

We consider an investment in Valneva to be a high-risk investment. Although Valneva has two vaccines that are approved in several major markets, it is unclear if the Company will be able to increase their sales of these products enough to overcome their debt obligations and operating expenses. In addition, there is no guarantee that Valneva’s vaccine candidates will be able to achieve regulatory approval in their targeted markets. Valneva has not reached profitability and may need to seek additional financing in the future. The vaccine market is competitive and susceptible to pricing pressures, and unknown competitors may emerge.
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