

VALNEVA SE Gerland Plaza Techsud 70, Rue Saint-Jean-de-Dieu 69007 Lyon, *France* 

# Valneva Announces New EB66<sup>®</sup> Clinical Development License Agreement with International AIDS Vaccine Initiative for Preventive HIV Vaccine

**Lyon (France), October 2, 2013** – Valneva SE (Valneva), a European biotechnology company focused on vaccines and antibodies research and development, announced today that it has licensed the use of its EB66<sup>®</sup> cell line to the International AIDS Vaccine Initiative (IAVI) for the evaluation and development of a preventive HIV vaccine candidate in clinical trials.

The agreement is a landmark in Valneva's history, as it is the first time the company has given dual rights to a non-profit organization to perform both research and clinical studies using its technology. Valneva has historically separated the two functions in its licensing agreements.

EB66<sup>®</sup> is a proprietary cell-based technology for producing human and veterinary vaccines. The license allows IAVI to use Valvena's EB66<sup>®</sup> cell line through Phase II study of a vector-based vaccine candidate derived from a modified version of the canine distemper virus (CDV). The agreement was signed following a successful proof-of-concept demonstration by Valneva for the EB66<sup>®</sup> cell line technology.

Thomas Lingelbach, President and Chief Executive Officer, and Franck Grimaud, President and Chief Business Officer of Valneva, said, "It is of great importance for Valneva that the company contributes to the advancement of vaccines against global health threats. We are very excited to work with a first-class organization like IAVI, and we look forward to their progress in advancing this novel HIV vaccine candidate."

Christopher Parks, Senior Director of Viral Vaccines and Deputy Director of the Design and Development Lab at IAVI, added: "Our licensing agreement with Valneva gives IAVI access to an exciting technology in vaccine design. We look forward to working with Valneva on our CDV candidate as part of our broad pipeline of novel HIV vaccine candidates."

The CDV vector is being developed with support from the United States Agency for International Development (USAID) and a Collaboration for AIDS Vaccine Discovery grant from the Bill and Melinda Gates Foundation.

Financial terms of this non-exclusive agreement were not disclosed. If successful, the program could lead to a commercial license agreement.

Contacts:

Valneva SE

Laetitia Bachelot Fontaine





Communications@valneva.com T +33 2 28 07 37 10 M + 33 6 45 16 70 99

International AIDS Vaccine Initiative (IAVI) – U.S. & International
Arne Naeveke, PhD
T +1 212 847 1055
ANaeveke@iavi.org

### Europe

Hester Kuipers
Tel: +31 20 521 0343
HKuipers@iavi.org

### **About Valneva SE**

Valneva is a new European biotech company focused on vaccine development and antibody discovery. It was created in 2013 through the merger between Intercell AG and Vivalis SA. Valneva's mission is to excel in both antibody discovery, and vaccine development and commercialization, either through inhouse programs or in collaboration with industrial partners using innovative technologies developed by the company. Valneva generates diversified revenue from both its marketed product, a vaccine for the prevention of Japanese encephalitis (IXIARO®), commercial partnerships around a portfolio of product candidates (in-house and partnered), and licensed technology platforms (EB66® cell line, VIVA|Screen<sup>TM</sup> antibody discovery technology, and the IC31® adjuvant) developed by Valneva that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquartered in Lyon, France, the company employs approximately 350 people in France, Austria, Scotland, the United States, and Japan. The internationally experienced management team has a proven track-record across research, development, manufacturing, and commercialization

# About the EB66® Cell Line

Valneva's EB66® cell line is a highly efficient platform for vaccine production. It is derived from duck embryonic stem cells and today represents the only alternative to chicken eggs for large scale manufacturing of human and veterinary vaccines. To date, the company has more than 35 research and commercial agreements with the world's largest pharmaceutical companies to license its EB66® technology. The first veterinary vaccine using the EB66® technology received market approval in 2012 and a new drug application (NDA) for human pandemic influenza is currently under review in Japan.

## www.valneva.com

# **About AIDS Vaccines**

An AIDS vaccine is urgently needed to help control the AIDS pandemic and stop the spread of HIV. Worldwide, 35 million people are living with HIV, and 6,300 people are newly infected with the virus every day. Clinical and laboratory evidence suggests that the immune system can be harnessed to prevent or control HIV infection. The effort to develop an AIDS vaccine is informed by that evidence and driven by partnerships between academic, government, commercial and non-profit institutions from around the world, working together toward the common goal of ending AIDS.



### **About the International AIDS Vaccine Initiative**

The International AIDS Vaccine Initiative (IAVI) is a global not-for-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Founded in 1996, IAVI works with partners in 25 countries to research, design and develop AIDS vaccine candidates. In addition, IAVI conducts policy analyses and serves as an advocate for the AIDS vaccine field. IAVI supports a comprehensive approach to addressing HIV and AIDS that balances the expansion and strengthening of existing HIV-prevention and treatment programs with targeted investments in the design and development of new tools to prevent HIV. IAVI is dedicated to ensuring that a future AIDS vaccine will be available and accessible to all who need it. IAVI relies on the generous donations from governments, private individuals, corporations and foundations to carry out its mission. For more information, please visit www.iavi.org.

# **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 their in 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 during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.