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

Valneva Announces Publication of First Phase II Data of Tuberculosis Vaccine Candidate Formulated with IC31® Adjuvant:

Clinical Trial in HIV-infected Adults Showed Good Safety and Immunogenicity

Lyon (France), December 10, 2014 – European biotechnology company Valneva SE ("Valneva") announced today that the Statens Serum Institut's (SSI) novel Tuberculosis (TB) vaccine candidate H1/IC31® formulated with Valneva's proprietary adjuvant IC31® showed good safety and immunogenicity in Phase II clinical trial in HIV-infected adults.

The results of the randomized, double-blind, clinical phase II trial initiated and led by Prof Churchyard from the Aurum Institute NPC, South Africa, were published in an article written by Dr. Reither of the Swiss Tropical and Public Health Institute (TPH) in the scientific online publication PLOS ONE*. The aim of the trial, which was conducted in South Africa and Tanzania, was to evaluate the immunogenicity and safety of two doses of the TB vaccine candidate H1/IC31® in 48 HIV-positive adults (between 18 and 55 years of age).

According to the article, the vaccine candidate H1/IC31® was well tolerated and safe in HIV-infected adults with a CD4+ Lymphocyte count greater than 350 cells/mm^3. It did not affect HIV viral load and induced a specific and durable immune response against TB. HIV-infected patients are more at risk than others to become infected with TB as their immune system is already weakened. According to the World Health Organization (WHO), TB is one of the leading causes of death among people living with HIV causing one fifth of all deaths.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva commented, "These first Phase II results are very encouraging and further validate the performances of our proprietary IC31® adjuvant. We are very proud that our technology is playing a key role in the development of a much-needed novel efficient TB vaccine".

H1/IC31® is a recombinant subunit vaccine based on two important TB antigens (Ag85B and ESAT-6) developed by SSI and formulated with Valneva's proprietary adjuvant IC31®, ultimately targeted toward adults and adolescents.

SSI is conducting a second Phase II clinical study to assess the safety and immunogenicity of the H1/IC31® vaccine candidate in 240 adolescents. Further Phase I or I/II trials are also being conducted by SSI and their partners, including Sanofi Pasteur and AERAS, with two other vaccine candidates formulated with Valneva's IC31® adjuvant. Valneva is entitled to receive a share of the profits coming from SSI's revenues related to the use of IC31®.

The PLOS ONE article is freely accessible online at: http://dx.plos.org/10.1371/journal.pone.0114602

**Reither K, Katsoulis L, Beattie T, Gardiner N, Lenz N, et al. (2014) Safety and Immunogenicity of H1/IC31H, an Adjuvanted TB Subunit Vaccine, in HIV-Infected Adults with CD4+ Lymphocyte Counts Greater than 350 cells/mm3: A Phase II, Multi-Centre, Double-Blind, Randomized, Placebo-Controlled Trial. PLoS ONE 9(12): e114602. doi:10.1371/journal.pone.0114602*

About Tuberculosis
Tuberculosis (TB) remains a global public health problem. One third of humankind is infected with Mycobacterium tuberculosis *(M.tb)*, which according to the World Health Organization (WHO) led to almost 8.6 million new active TB cases and 1.3 million TB deaths in 2012. Mycobacterium bovis Bacille Calmette-Guérin (BCG), the only currently licensed TB vaccine, is effective in preventing severe progressive disease in children but has limited impact on pulmonary adult TB, the driving force of the TB global pandemic. Consequently, there is an urgent need to develop safe and efficacious TB vaccines to accelerate progress towards TB elimination.

About IC31®
Valneva's IC31® adjuvant is a unique synthetic adjuvant combining the immuno-stimulating properties of an antimicrobial peptide (KLK) and an oligodeoxynucleotide (ODN1a). Eight human clinical trials have shown IC31® to be a safe and immunogenic adjuvant in study volunteers. Those receiving IC31® have reported good local tolerance with no systemic adverse effects during clinical studies.

About Valneva SE
Valneva is a European biotech company focused on vaccine development and antibody discovery. It was formed in 2013 through the merger of Intercell AG and Vivalis SA. Valneva's mission is to excel in both antibody discovery, and vaccine development and commercialization, either through in-house 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® antibody discovery technology, and the IC31® adjuvant) that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquarted in Lyon, France, the company employs approximately 270 people in France, Austria, Scotland, the United States, and Japan. www.valneva.com

Valneva Media Contact
Laetitia Bachelot-Fontaine
Investor Relations & Corporate Communications Manager
Communications@valneva.com
T +33 (0)228 07 37 10

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.