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Valneva provides update on DUKORAL® vaccine in Canada

- *Business transition and integration of the newly acquired DUKORAL® and Nordics vaccine distribution business largely completed*
- *Health Canada requested changes to product monograph for DUKORAL® in Canada*
- *Valneva and the seller agree on modifications to the purchase agreement including an adjustment to the purchase price*
- *Valneva will continue to invest in growing the product by way of promotional efforts and geographical expansion, focusing its own dedicated resources on key countries*

Lyon (France), December 23, 2015 – Valneva SE ("Valneva"), a leading pure-play vaccine company, today provides an update on its acquired DUKORAL® vaccine.

The transition of the business from Crucell Holland B.V., the seller, including both the gradual takeover of transitional services and the full transfer and installation of all acquired assets, has been largely completed. Regulatory licenses together with other processes and systems are being transferred and integrated into Valneva and its newly created affiliates, including Valneva Canada Inc. Synergies with the rest of the Valneva Group are being implemented and are expected to have a positive financial impact in 2016. In addition, Valneva will implement changes to the DUKORAL® label in Canada, with revised indications that allow using the vaccine to prevent cholera and LT-ETEC-caused diarrhea.

Valneva applied for such changes to the product monograph following a product review by Health Canada, the federal department overseeing pharmaceutical products licensed in Canada. The agency felt that this revised product indication was required to ensure proper usage of the vaccine by Canadians traveling to at-risk areas.

Valneva expects that this change in product indications and changes to promotional campaigns may negatively impact DUKORAL® sales in Canada going forward. Although Valneva will continue to invest in growing the product by way of promotional efforts and geographical expansion outside of Canada, Valneva expects that the potential for the product will be more limited than initially expected. Valneva anticipates however that the product will generate positive cash-flows in 2016 and beyond.

In order to reflect the business changes resulting from the adjustments to the Dukoral® label in Canada, the seller and Valneva have agreed on certain amendments to the purchase agreement including an adjustment to the purchase price.

The initially paid purchase price will be reduced by an amount equivalent to the EUR 15m acquisition debt incurred by Valneva plus any pre-payment fees. Furthermore,

the seller waived the outstanding milestone payment due from Valneva in connection with the acquisition.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, Deputy CEO of Valneva, commented, “Although the modification of the DUKORAL® label may impact the sales potential of the vaccine in Canada, the strategic merits that supported the acquisition of DUKORAL® remain unchanged. This business is expected to be financially sustainable and to represent a complementary fit in support of Valneva’s strategy to build a leading, financially self-sustainable pure-play vaccine Company, balancing growth from commercial product contributions and investments in promising R&D vaccine programs. Our previous outlook for reaching operational break-even remains unchanged”.

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About DUKORAL®

On a pro-forma basis DUKORAL® sales were EUR 25.5 m in 2014 of which 54% resulted from sales in Canada.

DUKORAL® is an oral vaccine indicated for active immunization against cholera and, in some countries, also indicated against LT-ETEC-caused diarrhea. The vaccine is indicated for adults and children from 2 years of age who will be visiting endemic/epidemic areas. DUKORAL® was first granted authorization for use in Sweden in 1991. In 2004, DUKORAL® was granted a marketing authorization by the European commission for European Union members (including Norway and Iceland) and was pre-qualified by the World Health Organization. Cholera is an acute diarrheal infection caused by ingestion of food or water contaminated with the bacterium V. cholerae. An estimated 3 to 5 million cholera cases occur each year and about 100,000 to 120,000 people die from cholera each year.

About Valneva SE

Valneva is a fully-integrated vaccine company that specializes in the development, manufacture and commercialization of innovative vaccines with a mission to protect people from infectious diseases through preventative medicine.
The Company seeks financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability.

Valneva's portfolio includes two commercial vaccines for travelers: one for the prevention of Japanese Encephalitis (IXIARO®) and the second (DUKORAL®) indicated for the prevention of Cholera and, in some countries, prevention of diarrhea caused by LT-ETEC. The Company has proprietary vaccines in development including candidates against Pseudomonas aeruginosa, Clostridium difficile and Lyme Borreliosis. 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® vaccine production cell line, IC31® adjuvant).
Valneva is listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Scotland and Sweden with approximately 400 employees. More information is available at www.valneva.com.

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.