

## Valneva Announces A New EB66<sup>®</sup> Cell Line Agreement with Delta-Vir

**Lyon (France), September 12, 2013** – Valneva SE (Valneva), a European biotechnology company focused on vaccines and antibodies, announced today that it has signed an agreement with German biopharmaceutical company Delta-Vir GmbH, for the production of Newcastle Disease Virus (NDV), which is a component of its novel cancer therapy vaccine, in Valneva's EB66<sup>®</sup> production cell line.

The deal, which also includes a commercial option, will allow Delta-Vir to enter clinical trials with its first vaccine candidate DVG01, which has been developed to treat patients with glioblastoma multiforme (GBM). GBM is the most aggressive form of brain cancer which leads to the death of around 7,200 people per year in Europe, with the global market for this indication estimated at around EUR 2.58 billion\*.

Delta-Vir's autologous cell therapy, which has already been used in human patients, appears to be safe with no adverse events being reported to date. If successful, DVG01 will be the first live virus produced in the EB66<sup>®</sup> cell line administered to humans. Delta-Vir expects to file a Clinical Trial Application (CTA) in Europe for a confirmatory clinical trial in the second half of 2014.

The new agreement broadens the collaboration between Delta-Vir and Valneva, who have been working together since 2011 to manufacture clinical grade material of NDV under Good Manufacturing Practices (GMP) using Valneva's EB66<sup>®</sup> cell line technology.

"We are very excited to take this next step forward with Valneva and it confirms our experience of EB66<sup>®</sup> as an excellent cell line and well suited to the production of NDV", said **Ingo Wilke, co-founder and CSO of Delta-Vir**.

"We are looking forward to the success of Delta-Vir's GBM vaccine as, apart from radiation and chemotherapy, there is no market-approved therapy to treat this rapidly terminal disease. The fact that DVG01 has already shown good safety data is very promising for the product's future," said **Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva**.

Besides GBM, Delta-Vir is also planning to develop and launch follow-on cancer products using Valneva's EB66<sup>®</sup> cell line, for larger cancer markets such as prostate cancer, a EUR 23 billion global market\*.

Financial terms of the agreement were not disclosed but do include upfront and annual maintenance payments.



\* Source: Delta-Vir

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**About Valneva SE**

Valneva is a new European biotech company focused on vaccine development and antibody discovery. It was formed 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 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<sup>®</sup>), commercial partnerships around a portfolio of product candidates (in-house and partnered), and licensed technology platforms (EB66<sup>®</sup> cell line, VIVA|Screen<sup>™</sup> antibody discovery technology, and the IC31<sup>®</sup> 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

[www.valneva.com](http://www.valneva.com)

**About EB66<sup>®</sup> Cell Line**

Valneva's EB66<sup>®</sup> cell line is a highly efficient platform for vaccine production. It is derived from duck embryonic stem cells and today represents a validated 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<sup>®</sup> technology. The first veterinary vaccine using the EB66<sup>®</sup> technology received market approval in 2012 and a new drug application (NDA) for human pandemic influenza is currently under review in Japan.

**About Delta-Vir**

Delta-Vir is a biopharmaceutical company founded to progress novel anti-tumor vaccines incorporating oncolytic virus. Based in Köln, Germany, Delta-Vir was initiated in 2011 out of the IOZK (Immunologisches und Oncologisches Zentrum Köln) to build on the promising results observed when the vaccine was used as a compassionate anti-cancer treatment in Germany. The company's objective is to seek regulatory approval for this therapy in order to enable the treatment to be more readily available to a wider range of patients.

<http://www.delta-vir.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 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.