Pfizer Logo

Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate

Monday, March 08, 2021 - 08:30am

- ***The Phase 2 study will include both adult and pediatric subjects with an aim to support acceleration of the vaccine candidate's pediatric program***
- ***VLA15 will be tested at two different schedules (Month 0-2-6 or Month 0-6) receiving the selected dose of 180µg***
- ***VLA15 is the only Lyme disease vaccine candidate in active clinical development***

Saint-Herblain (France) and New York, NY, March 8, 2021 – Valneva SE ("Valneva"), a specialty vaccine company focused on prevention of diseases with major unmet needs, and Pfizer Inc. (NYSE: PFE) today announced initiation of study VLA15-221. The VLA15-221 study builds on previous positive Phase 2 studies, incorporates new dose regimens and is anticipated to be the final Phase 2 study readout before a decision to progress into pivotal Phase 3 studies.

As announced in December 2020[1], VLA15-221 is a randomized, observer-blind, placebo-controlled Phase 2 study. It will be the first VLA15 study to include a pediatric population (aged 5-17 years). Overall, the study will enroll approximately 600 healthy participants (aged 5-65 years) who will receive VLA15 or placebo. It will compare the three-dose vaccination schedule (Month 0-2-6) with a two-dose schedule (Month 0-6).

"We are excited to be part of the Lyme disease vaccine development program with Valneva. We hope this Phase 2 trial, with a simplified schedule, will provide evidence that the investigational vaccine can be used in populations that are at risk of contracting Lyme disease, potentially including children age five years and older," ***said Kathrin Jansen, Senior Vice President and Head of Pfizer Vaccine Research and Development.***

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva commented*, "This trial initiation marks an important step in the development of VLA15 toward a potential licensure. Including a pediatric population in Phase 2 means we could, if successful, add this population to the Phase 3 research program, to potentially offer a vaccine for Lyme disease that may help prevent disease in both adults and children, if approved. We are pleased that, together with our partner Pfizer, we have decided to pursue this development while preparing for a potential Phase 3 start."*

Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15[2]. Under the terms of the agreement, first subject, first dose in this study will trigger a milestone payment of $10 million from Pfizer to Valneva.

About VLA 15

VLA15 is the only active Lyme disease vaccine candidate in clinical development today, and covers six serotypes that are prevalent in North America and Europe. This investigational multivalent protein subunit

vaccine targets the outer surface protein A (OspA) of Borrelia, an established mechanism of action for a Lyme disease vaccine. OspA is one of the most dominant surface proteins expressed by the bacteria when present in a tick. VLA15 has demonstrated strong immunogenicity and safety data in pre-clinical and clinical studies so far. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017 [3].

Valneva and Pfizer announced a collaboration for VLA15's development and commercialization at the end of April 2020. The two companies are working closely together on the next development steps.

About Clinical Study VLA15-221

VLA15-221 is a randomized, observer-blind, placebo-controlled Phase 2 study. It is the first clinical study with VLA15 that enrolls a pediatric population aged 5 years and older.

A total of approximately 600 participants will receive VLA15 at two different immunization schedules (Month 0-2-6 or Month 0-6, 200 volunteers each) or placebo (Month 0-2-6, 200 volunteers). Vaccinees will receive VLA15 at a dose of 180µg, which was selected based on data generated in the two previous Phase 2 studies. The main safety and immunogenicity readout (Primary Endpoint analysis) will be at Month 7, where peak antibody titers are expected. A subset of participants will receive a booster dose of VLA15 or placebo at Month 18 (Booster Phase) and will be followed up for further three years to monitor antibody persistence.

VLA15 will be tested as an alum-adjuvanted formulation and administered intramuscularly. The study will be conducted at sites which are located in areas where Lyme disease is endemic and will enroll volunteers with a cleared past infection with *Borrelia burgdorferi*, the bacteria that cause Lyme disease, as well as *B. burgdorferi* naïve volunteers.

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia* bacteria *burgdorferi sensu* lato transmitted to humans by infected *Ixodes* ticks[4]. It is considered the most common vector borne illness in the Northern Hemisphere. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 Americans are diagnosed and treated for Lyme disease each year[5] with at least a further 200,000 cases in Europe[6]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called *Erythema migrans* or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system. The medical need for vaccination against Lyme disease is steadily increasing as the disease footprint widens[7].

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on

Facebook at Facebook.com/Pfizer.

Pfizer Forward-Looking Statements

The information contained in this release is as of March 8, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a Lyme disease vaccine candidate, VLA15, and a collaboration between Pfizer and Valneva for VLA15, including their potential benefits and a potential phase 3 start, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for VLA15; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether VLA15 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VLA15; the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About Valneva SE

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. We take a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

Valneva 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.

Pfizer Contacts

Media Contact: Jerica Pitts

+1 (347) 224-9084

Jerica.Pitts@pfizer.com

Investor Contact: Bryan Dunn

+1 (212) 733-8917

Bryan.Dunn@pfizer.com

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine

Director Investor Relations & Corporate Communications

M +33 (0)6 4516 7099

investors@valneva.com

# # #

[1]Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate

[2] Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

[3] Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15

[4] Stanek et al. 2012, The Lancet 379:461–473

[5] Source: https://www.cdc.gov/lyme/stats/humancases.html

[6] Valneva Data on File: Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report

[7] New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017 https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/