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“Our COVID-19 Vax Efficacy is Promising; Lyme disease & Chikungunya Shots in pipeline"

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Headquartered in France, Valneva, is an established European specialty vaccine company that has already commercialised the Japanese encephalitis vaccine IXIARO/JESPECT and the oral cholera vaccine DUKORAL. It has recently developed VLA2001, a COVID-19 vaccine that stimulates an immune response to target the entire virus, rather than just its spike proteins. With such claims, VLA2001 could become the top-choice as booster shot for Asian countries, in addition to providing overall protection as the primary two-dose schedule. BioSpectrum Asia spoke to Dr Juan Carlos Jaramillo, Chief Medical Officer, Valneva to find out more about the new vaccine.

What are the unique highlights of the COVID-19 vaccine- VLA2001 under trial?

While different companies have taken various approaches to developing vaccines against COVID-19, such as using viral vectors and mRNA, we have developed a whole virus, inactivated, adjuvanted vaccine. VLA2001 is the only inactivated, adjuvanted, whole virus COVID-19 vaccine candidate in clinical development in Europe. It is produced on Valneva’s established Vero-cell platform, leveraging the manufacturing technology for Valneva’s licensed Japanese encephalitis vaccine. Furthermore, the vaccine consists of inactivated whole virus particles of SARS-CoV-2 with high S-protein density, in combination with two adjuvants, alum and CpG 1018.

What's the technology being deployed?

We have successfully developed and manufactured another inactivated vaccine – our FDA/EMA-approved Japanese encephalitis vaccine – and we have leveraged the manufacturing technology used for that vaccine to produce our inactivated COVID-19 vaccine candidate, VLA2001. Inactivated vaccines are a well-established technology that has been used over the last 70 years to vaccinate billions of people – for seasonal flu, polio, and rabies. In an inactivated vaccine, the virus is killed but the whole virus envelope is preserved so compared to vaccines targeting only the spike protein, inactivated vaccines have the potential to provide an added benefit by boosting T-cell responses against additional SARS-CoV-2 proteins.

We reported positive Phase 3 results for VLA2001 demonstrating that our COVID-19 vaccine candidate induced broad T-cell responses against multiple viral proteins (S, N and M proteins) while showing a significantly better tolerability profile compared to an EMA-approved COVID-19 vaccine. In addition, our first homologous booster data showed that a third dose of VLA2001 significantly boosted immunity in participants who had received two doses of VLA2001 as primary vaccination; and in January 2022, laboratory studies confirmed VLA2001's ability to neutralise the Omicron and Delta variants and its potential for broad-spectrum protection with 100 per cent of tested serum samples presenting neutralising antibodies against the Delta variant and 87 per cent against the Omicron variant (B.1.1.529 lineage).

When do you plan to launch the vaccine in the market, and which countries are you targeting?

Valneva believes its inactivated vaccine can make a significant contribution to the ongoing fight against the pandemic and is pursuing opportunities to provide VLA2001 in different markets, subject to regulatory approval.

Following positive Phase 3 trial results for VLA2001, Valneva remains focused on achieving regulatory approvals; reviews are underway with the EU's EMA, UK's MHRA, and Bahrain's NHRA. So far, we have signed an Advance Purchase Agreement with the European Commission to supply up to 60 million doses of VLA2001 over two years; and with the Kingdom of Bahrain to supply one million doses.

Do you foresee any regulatory challenges?

Regulation is essential to determine whether a product is effective, safe, and patient-centred. At Valneva, we produce our solutions with the highest quality and standards and will continue to work closely with governments and regulatory bodies to ensure that VLA2001 is effective and safe for all to use.

What are the specific plans of launching the vaccine in the Asian market?

Discussions with potential customers are commercially sensitive and so we cannot comment on those. However, following VLA2001's positive Phase 3 trial results, Valneva remains focused on securing regulatory approvals and providing VLA2001 in different markets as we believe that everyone should have access to the technology best suited to protect themselves against the virus.

How could VLA2001 be a top-choice booster shot for Asian countries, in addition to providing overall protection as the primary two-dose schedule?

The duration of protection induced by current vaccines suggest that repeated doses will be needed to maintain higher levels of antibodies. Valneva's first positive homologous booster data showed excellent immune response after administration of a VLA2001 booster dose seven to eight months after the second dose of primary vaccination. Valneva also launched a booster extension to its Phase 3 study which is intended to provide both homologous and first heterologous booster data.

Are you planning to develop more vaccines for infectious diseases in the future? If yes, what are the launch plans?

Valneva's Lyme disease programme is the only one in clinical development worldwide and our chikungunya vaccine candidate is the only one that has demonstrated efficacy and safety in Phase 3 trials.

We are also making significant developments and recently reported further positive Phase 2 data for our Lyme disease vaccine candidate, VLA15, as we look to proceed with a three-dose primary series vaccination schedule in a planned Phase 3 clinical trial in the third quarter this year.

For our single-shot chikungunya vaccine candidate, VLA1553, following positive Phase 3 results in adults, we initiated Phase 3 trial in adolescents to support the label extension in this age group following a potential initial regulatory approval in adults from the US Food and Drugs Administration (FDA). It is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations.

What are your views on the COVID-19 vaccine wastage, and how can that be addressed?

Unfortunately, millions of vaccines have been discarded, lost, damaged, or destroyed. A certain amount of waste is expected and is something that is beyond anyone's control, such as spillage, expiration and global supply chain constraints.

VLA2001 is expected to have a two-dose regimen and conform with standard cold chain requirements (2 degrees to 8 degrees centigrade), making it easier to store and distribute. Ultimately, Valneva's goal is to get as many people vaccinated as possible so that they have the necessary protection against COVID-19.

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