COVID-19

WHAT IS COVID-19?

COVID-19 is the infectious disease caused by the new coronavirus (SARS-CoV-2) identified in late 2019. COVID-19 is affecting many countries globally and has been declared a pandemic by the World Health Organization (WHO).[1] To date, there have been over 5 million COVID-19 related deaths reported worldwide.[2]

SYMPTOMS & DIAGNOSIS

Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness[3]. The most common symptoms of COVID-19 are fever, dry cough and tiredness. Other symptoms that are less common and may affect some patients include muscle or joint pain, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste and/or smell or different types of skin rash[1].

Age accounts for most of the increase in risk of severe COVID-19. People over 60 years of age and those with multiple underlying health conditions (e.g., hypertension, diabetes, cardiovascular disease, chronic respiratory disease and immune suppression) are considered to be more at risk of developing severe symptoms. Men in these groups also appear to be at a slightly higher risk than women[4].

SPREAD OF INFECTION

People can contract COVID-19 from others who have the virus. The disease spreads primarily from person-to-person through small droplets from the nose or mouth, which are expelled when a person with COVID-19 coughs, sneezes or speaks. Droplets can be inhaled or can land on surfaces that others come into contact with and are then infected when they touch their nose, mouth or eyes. The virus can survive on surfaces from anything between a few hours (copper, cardboard) to a number of days (plastic and stainless steel).[5]

TREATMENT & PREVENTION

Several vaccines are currently approved for full and early or limited use. However, achievement of herd immunity would require a very high proportion of people either vaccinated or recovered from infection in every community, every social group and every geographical location to have lasting protection against even mild disease[6]. The treatment for people who are hospitalized with severe COVID-19 disease is largely supportive (e.g., oxygen therapy, management of fluids), mostly using a symptomatic approach[4]. Several medicines have shown to be beneficial for people with severe disease or under specific circumstances in clinical trials[4]. Protective measures remain important, such as covering coughs and sneezes, wearing protective face masks, cleaning hands, avoiding touching your eyes, mouth and nose and practicing social/physical distancing[3].

VALNEVA'S VACCINE CANDIDATE - VLA2001

- Inactivated
- Adjuvanted with Alum and CpG 1018
- Highly-purified
- Whole virus candidate
- Vero-cell based
- Using the manufacturing platform of Valneva's commercial Japanese encephalitis (JE) vaccine

Phase 3 trials

Over 4,000 adult volunteers were recruited[7] for Valneva's Phase 3 immunogenicity trial, "Cov-Compare." The trial compares VLA2001 to the Vaxzevria vaccine (AstraZeneca), which has already received conditional marketing authorization in the UK and the EU, amongst others[8].

Valneva reported positive topline Phase 3 results from the "Cov-Compare" trial[9]:

- The VLA2001 vaccine candidate successfully met both co-primary endpoints:
  - Superior neutralizing antibody titer levels compared to AstraZeneca's AZD1222
  - Neutralizing antibody seroconversion rate above 95%
- VLA2001 was generally well tolerated, demonstrating a significantly better tolerability profile than AZD1222
- Complete absence of severe COVID-19 cases, despite circulating variants (predominantly Delta)
- VLA2001 induced broad T-cell responses against the S, M and N proteins

Valneva has initiated additional clinical trials to support future approval in further age groups, in addition to adults. Valneva completed recruitment of 306 volunteers aged 56 years and older in New Zealand[10] into its VLA2001-304 trial and expects topline data in early 2022. Valneva has commenced recruiting adolescents as an expansion of the Cov-Compare trial[11]. The Company is preparing for trials in children (5-12 years of age) and a Valneva sponsored booster trial to evaluate VLA2001's booster performance for people in need of a booster.

Rolling submission with MHRA / EMA

Valneva remains focused on achieving regulatory approvals of VLA2001 following its positive Phase 3 trial results. The Company initiated a rolling submission with the UK Medicines and Healthcare products Regulatory Agency (MHRA) in August 2021 and a rolling review with the European Medicines Agency (EMA) in December 2021. Potential regulatory approvals are expected in the first quarter of 2022.

Designed & manufactured in Europe

VLA2001 was developed by Valneva's R&D teams in France & Austria. It is the only inactivated, adjuvanted whole virus COVID-19 vaccine candidate in clinical trials in Europe.

Valneva's facility in Livingston, Scotland has been producing FDA/EMA/MHRA approved commercial-grade travel vaccines for more than a decade.

Initially dedicated to the production of the Company's cholera vaccine, Valneva's facility in Solna has been expanding its capacity in order to provide full fill and finish operations for the VLA2001 vaccine (subject to authorization).

Valneva expects to have capacity to produce over a hundred million doses of vaccine per annum through a combination of in-house production and CMO capacity.

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8. Valneva Initiates Phase 3 Clinical Trial for its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001
9. Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001
10. Valneva Completes Recruitment of Elderly Participants in Phase 3 Trial of its Inactivated COVID-19 Vaccine
11. Valneva Continues Expansion of Clinical Trials of its Inactivated COVID-19 Vaccine Candidate VLA2001