Medicago and GSK announce positive interim Phase 2 results for adjuvanted COVID-19 vaccine candidate

GSK

PUBLISHED MAY 18, 2021 BY GSK

For media and investors only

- Similar antibody response in adults and in the elderly after two doses
- Neutralizing antibody responses were ten times higher than in people recovering from COVID-19
- No related severe adverse events reported

Medicago, a biopharmaceutical company headquartered in Quebec City, and GlaxoSmithKline (GSK) are pleased to report positive interim Phase 2 clinical trial safety and immunogenicity data for Medicago's plant-derived COVID-19 vaccine candidate, which has been tested in combination with GSK's pandemic adjuvant.

These results are part of the ongoing Phase 2/3 study and reiterate the promising profile observed during Phase 1 testing. Immunogenicity, as measured by the neutralising antibody titer, was high: about 10 times higher than those in a panel of sera from patients recovering from COVID-19. No related severe adverse events were reported and reactogenicity was generally mild to moderate and short in duration.

We are very excited to see such positive results from the Phase 2 data. After two doses, the adjuvanted vaccine candidate induced robust neutralizing antibody and cellular immune responses in all subjects, irrespective of age," said Nathalie Landry, Executive Vice President, Scientific and Medical Affairs at Medicago. "These results give us confidence as we continue to move forward with our Phase 3 clinical trial. We hope to add

another tool in the global fight against COVID-19, particularly as cross-protection emerges as an important consideration in vaccination efforts worldwide.

Thomas Breuer, Chief Medical Officer, GSK Vaccines said,

We are delighted to see that the results suggest a very strong immune response. Medicago's COVID-19 vaccine candidate combined with GSK's pandemic adjuvant was also well tolerated, reinforcing its potential benefits. We now look forward to the outcome of the ongoing Phase 3 trial of this refrigerator-stable vaccine candidate as the next step forward in our contribution to the global response to the pandemic.

The Phase 3 trial of the vaccine candidate launched on 16 March 2021. Trial sites are currently enrolling subjects in Canada, the United States, the United Kingdom and Brazil, with additional sites expected to be added in the coming weeks. The vaccine candidate has received Fast Track designation by the FDA in the United States, and Health Canada has initiated a review of Medicago's COVID-19 rolling submission under the Interim Order.

About Phase 2: Results Summary

The interim data from Phase 2 in adults and in the elderly have been published on an online preprint server at MedRxiv.

- This publication focuses on presenting safety and tolerability results, and immunogenicity, as measured by neutralizing antibody (NAb) and cell mediated immunity (IFN-γ and IL-4 ELISpot) responses, in adults aged 18-64 (adults) and older adults aged 65+ (older adults).
- Medicago's vaccine candidate with GSK's pandemic adjuvant exhibited an acceptable safety profile and adverse events (AEs) were primarily mild or moderate and of transient duration.
- AEs in older adults were more limited than those observed in the adult population.
- Medicago's vaccine candidate with GSK's pandemic adjuvant induced a significant humoral immune response of similar strength in both age cohorts after two doses.

- The vaccine candidate induced a greater humoral response in adults than older adults after a single dose but after the second dose both age cohorts responded with NAb titers that were about 10 times higher than those in a panel of sera from patients recovering from COVID-19.

The Phase 2/3 study is a multi-portion design to confirm that the chosen formulation and dosing regimen of CoVLP (two doses of 3.75 µg CoVLP combined with GSK's pandemic adjuvant given 21 days apart) has an acceptable immunogenicity and safety profile in healthy adults 18-64 years of age, elderly subjects aged 65 and over and adults with comorbidities.

The Phase 2 portion of the trial was a randomized, observer-blind, placebo-controlled study to evaluate the safety and immunogenicity of the adjuvanted recombinant COVID-19 plant-derived vaccine candidate in subjects aged 18 and above. It was conducted in multiples sites in Canada and the United States in a population composed of healthy adults (18-64y), elderly adults (over 65y) and adults with comorbidities. Each age group enrolled up to 306 subjects randomized 5:1 to receive the adjuvanted CoVLP vaccine candidate: placebo and with 2:1 stratification in older adults (65-74 and ≥75). All subjects will be followed for a period of 12 months after the last vaccination for the assessment of safety and durability of the immune responses to the vaccine candidate which will be the final analysis.

The Phase 3 portion is an event-driven, randomized, observer-blinded, crossover placebo-controlled design that will evaluate the efficacy and safety of the CoVLP formulation, compared to placebo, in up to 30,000 subjects in North America, Latin America and Europe and within the same population.

GSK commitment to tackling COVID-19

GSK's response to COVID-19 has been one of the broadest in the industry, with three potential treatments in addition to our vaccine candidates in development with partner organisations.

GSK is collaborating with several organisations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to our work with Medicago, we recently announced positive Phase 2 data from our collaboration with Sanofi to develop an adjuvanted, protein-based vaccine candidate and expect to begin a Phase 3 trial in

Q2. An earlier stage collaboration with SK Bioscience is also ongoing. SK Bioscience receives funding from CEPI and the Bill and Melinda Gates Foundation to develop differentiated, affordable COVID-19 vaccines for supply globally through the COVAX facility. The use of an adjuvant can be of particular importance in a pandemic since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and contributing to protecting more people. Based on experience with other adjuvanted vaccines, there is potential for increased cross protection against COVID-19 variants which will be further studied.

GSK is also working with mRNA specialist, CureVac, to jointly develop next generation, multi-valent mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK will also support manufacturing of up to 100m doses of CureVac's first generation COVID-19 vaccine. GSK is also providing manufacturing support for up to 60m doses of Novavax' COVID-19 vaccine in the UK.

GSK is also exploring potential therapeutic or treatment options for COVID-19 patients. We are collaborating with Vir Biotechnology to develop existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options for COVID-19. We recently reported that an Independent Data Monitoring Committee recommended that the Phase 3 COMET-ICE trial evaluating VIR-7831 as monotherapy for the early treatment of COVID-19 in adults.

Medicago is on a mission to improve global public health using the power of plants. Founded in 1999 with the belief that innovative approaches and rigorous research would bring new solutions in healthcare, Medicago is a pioneer in plant-derived therapeutics. We are proudly rooted in Quebec, with manufacturing capacity in both Canada and the US. Our passionate and curious team of over 450 scientific experts and employees are dedicated to using our technology to provide rapid responses to emerging global health challenges, and to advancing therapeutics against life-threatening diseases worldwide.

For more information: www.medicago.com

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further

information please visit www.gsk.com/about-us.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

Press release distributed by Wire Association on behalf of GSK, on May 18, 2021. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/medicago-and-gsk-announce-positive-interim-phase-2-results-for-adjuvanted-covid-19-vaccine-candidate-1943

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk

Website: https://www.gsk.com/

Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK

Twitter - http://twitter.com/GSK

Youtube - http://www.youtube.com/GSK

Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/