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ASX Announcement

For immediate release

8 October 2020

CSL finalises agreement to supply 51 million doses of UQ COVID-19 vaccine candidate to Australia

CSL Limited (ASX:CSL; USOTC:CSLLY) today announces that its subsidiary, Seqirus, has signed a final agreement (Agreement) with the Commonwealth of Australia for the supply of 51 million doses of the University of Queensland-CSL COVID-19 vaccine candidate (V451), should clinical trials be successful. This follows the Company's announcement of 7 September 2020 advising that a binding Heads of Agreement had been entered into with the Australian Government.

The Agreement includes an up-front financial commitment from the Government to support the clinical and technical development activities that CSL will need to assume in order to progress V451, and, if clinical trials are successful, also secures access to onshore production and supply of the vaccine for Australia.

CSL has been working at pace to respond to the current COVID-19 pandemic and has invested significant resources in the rapid development and large-scale manufacture of V451, along with a number of other therapeutic programs. The Company previously advised the ASX of additional agreements entered into with the Australian Government and with AstraZeneca to produce approximately 30 million doses of the Oxford University/AstraZeneca vaccine candidate, AZD1222. The two vaccines work through different approaches, but can leverage many facets of the same manufacturing platform technology used by CSL to produce recombinant proteins.

The large-scale Phase 2b/3 clinical study for V451 is almost ready. It will be a randomised, observer-blinded, placebo-controlled study across numerous countries and >100 sites. The study will evaluate efficacy, immunogenicity and safety in adults aged 18 years and above.

Subject to progress in the current Phase 1 study, the first subject for the Phase 2b/3 would be enrolled in December 2020, with the goal completing recruitment by March 2021. We are committed to demonstrating the vaccine is safe and effective prior to availability in the market. Discussions have already commenced with the Australian Therapeutic Goods Administration (TGA) to ensure this goal is met, while also making the vaccine available to the Australian population in the shortest possible time.

In parallel, CSL is working to engage partner organisations to assist with production of further doses with the goal of providing broader access to the vaccine, should clinical trials be successful. The Company also continues to work with the Coalition for Epidemic Preparedness Innovations (CEPI) to fulfil our shared commitment to the program, which includes support for the COVAX Facility, a mechanism established by CEPI, the Global Alliance for Vaccines & Immunizations (Gavi) and the World Health Organisation (WHO) to rapidly accelerate the development, production and delivery of COVID-19 vaccines to support equitable access.

Given the considerable risk, effort, cost and uncertainty associated with the development of these novel vaccines, it is too early to calculate with any certainty the financial impact to the Company.

Authorised by
Fiona Mead
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FURTHER INFORMATION

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