



## Providence Therapeutics Reports PTX-COVID19-B, its mRNA Vaccine for COVID-19, Neutralizes SARS-CoV-2 and Variants of Concern, Including Delta

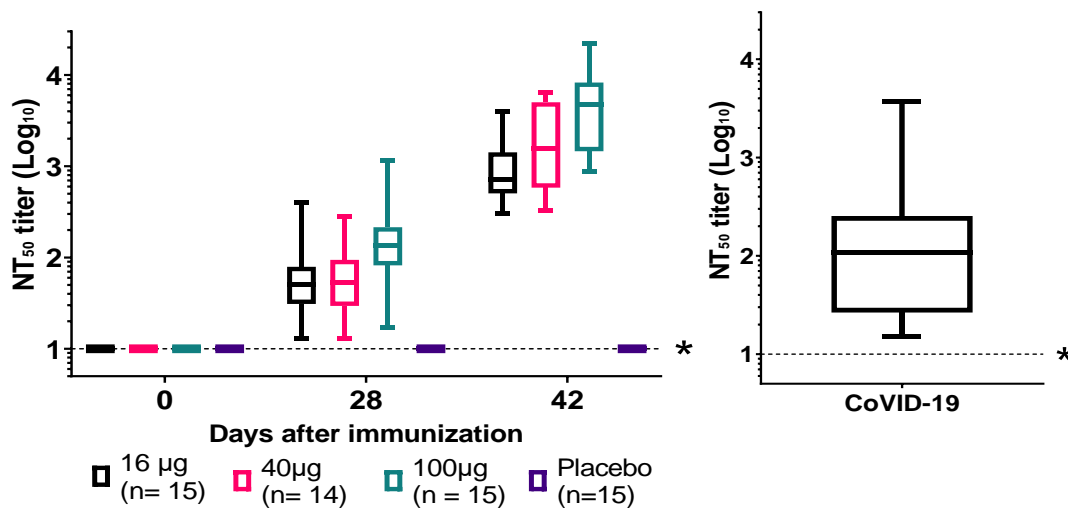
- PTX-COVID19-B dosed subjects from the Phase 1 clinical trial have high neutralization titers against the original strain of SARS-CoV-2 (G614). All subjects produced neutralizing antibodies after the first dose and the levels increased more than 10-fold after the second dose.

-The responses were dose-dependent and all had a level of neutralizing antibodies that would be predictive of protection from SARS-CoV-2.

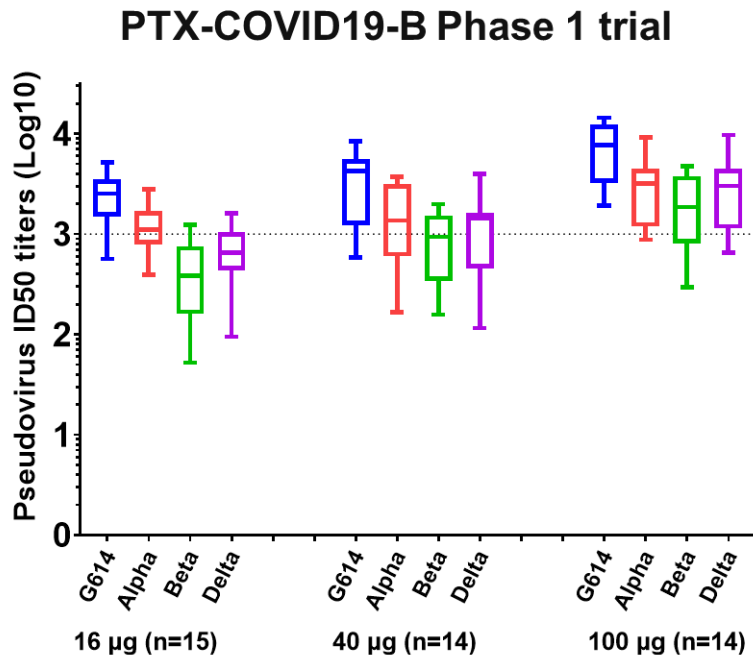
-Moreover, the sera from PTX-COVID19-B vaccinated subjects had high neutralization titers against the current variants of concern Alpha, Beta and Delta.

**Calgary, Alberta September 13, 2021** – Providence Therapeutics announced today additional results from its Phase 1 study, PRO-CL-001, of PTX-COVID19-B. Previously, Providence Therapeutics announced that the primary endpoints of safety, tolerability, and immunogenicity were met for the first in human placebo controlled, observer-blinded, randomized, ascending dose study in 60 healthy seronegative adults aged 18-64 for PTX-COVID19-B vaccine.

Today's announcement extends the immunogenicity data to include pseudovirus neutralization assays which are becoming the preferred standard for predicting efficacy of COVID-19 vaccines. Sera from all subjects dosed with PTX-COVID19-B demonstrated neutralizing activity by day 28 after only a single dose while none of the subjects dosed with a placebo generated neutralizing antibodies. The titers increased both with higher dose levels and over time when measured two weeks after the second dose. The neutralization titers by day 42 are over 1000 NT<sub>50</sub> (50% inhibition neutralization titer) and more than tenfold higher than the neutralization levels of COVID19 recovered patients as indicated by the validated neutralization assay.



The current wave of infections in Canada and worldwide is being driven by variants of SARS-CoV-2, particularly the recently emerged Delta variant which has been named a variant of concern (VOC) along with the Alpha, Beta and Gamma variants. Providence worked with the laboratory of Anne-Claude Gingras at Mount Sinai, Toronto to investigate the neutralizing capacity of the sera from subjects in the Phase 1 trial against three of the current VOCs; Alpha, Beta and Delta. The Inhibitory Dilution 50% (ID50) values of the sera were highest against the pseudovirus for the original strain, which is what the vaccine was designed against G614. In comparison, the geometric mean of the ID50 values against the three VOCs decline slightly but were maintain around the 1000 ID50 levels for the mid (40 µg) and the high dose (100 µg) cohorts. These neutralization levels against the VOC's are in the range that would be predicted as protective against the development of severe COVID-19 symptoms upon exposure to a SARS-CoV2 variants. Recently, the investigators at Mount Sinai, reported neutralization titers from Long Term Facility Housing (LTFH) staff members in Ontario that received two doses of the authorized mRNA vaccines using the same neutralization assays for Alpha, Beta and Gamma pseudoviruses (Abe K.T. Neutralizing antibody responses to SARS-CoV-2 variants in vaccinated Ontario long-term care home residents and workers. 2021 | medRxiv, <https://doi.org/10.1101/2021.08.06.2126172>). When compared to the reported neutralization levels from this study, PTX-COVID19-B induced neutralization ID50 levels against the original and VOC's comparable to the ones found in the staff vaccinated with approved mRNA vaccines.



PTX-COVID19-B mRNA vaccine can induce a robust neutralization against the original, Alpha, Beta and Delta variants. As such, the 40 µg dose level is now being evaluated in a Phase 2 clinical trial. The study will recruit 525 subjects and have important endpoints related to safety and immunogenicity.

Providence developed, manufactured, and tested this world-class vaccine in Canada. It licensed supporting lipid nanoparticle intellectual property that was invented in Canada from Genevant. The company looks forward to progressing through late-stage trials and is advancing business development discussions with partners globally, to ensure the access of affordable high-quality vaccines in countries where the need is greatest.

## **About Providence Therapeutics**

Providence is a leading Canadian clinical stage biotechnology company pioneering mRNA therapeutics and vaccines with operations in Calgary, Alberta and Toronto, Ontario. In response to a worldwide need for a COVID-19 vaccine, Providence expanded its focus beyond oncology therapies and devoted its energy and resources to develop a world-class mRNA vaccine for COVID-19. Providence is focused on serving the needs of Canada, and other countries that may be underserved by large pharmaceutical programs. For more information, please visit [providencetherapeutics.com](http://providencetherapeutics.com).

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of applicable securities laws including regarding the Providence's development of a potential vaccine against COVID-19, and the parameters and timing of the Phase 1 Study and planned Phase 2 study of PTX-COVID19-B. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Providence's control, and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: the fact that the safety and efficacy of PTX-COVID19-B has not yet been established; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; the fact that there are a limited number of commercial products utilizing mRNA technology approved for use; and the fact that the mRNA technology in use by Providence is still being developed and implemented. Except as required by law, Providence disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Providence's current expectations and speak only as of the date hereof.

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