

BIOLOGICS MANUFACTURING CENTRE AND NOVAVAX



In February 2021, the Government of Canada signed a memorandum of understanding (MOU) with Novavax, Inc. to pursue options to produce its COVID-19 vaccine candidate at the National Research Council of Canada's (NRC) Biologics Manufacturing Centre in Montréal, Québec, once both the vaccine candidate and the facility receive the required Health Canada approvals.

COLLABORATION AGREEMENT

In March, the NRC signed a collaboration agreement with Novavax to enable technology transfer to begin in early April.

The NRC and Novavax have been working closely together to prepare for the production of the Novavax vaccine at the Biologics Manufacturing Centre, including conducting the technology transfer to establish the step-by-step process of making the vaccine in the NRC's facility.

The related steps are being methodically outlined, tested and documented in line with industry practices, to ensure the process will consistently produce the intended product.

In parallel with the technology transfer process, a manufacturing agreement will be established between the Biologics Manufacturing Centre and Novavax before full-scale vaccine production can begin.

NOVAVAX OVERVIEW

Novavax, Inc. is a biotechnology company that promotes improved health globally through the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases.

Novavax is conducting late-stage clinical trials for NVX-CoV2373 COVID-19, a protein subunit based vaccine candidate against SARS-CoV-2, the virus that causes COVID-19.

Novavax remains focused on advancing development of NVX-CoV2373, including completion of filing for regulatory authorization in Canada.

PRODUCTION IN THE BIOLOGICS MANUFACTURING CENTRE

February 2021 – MOU with Novavax signed to pursue options to produce its COVID-19 vaccine at the Biologics Manufacturing Centre.

March 2021 – Vaccine candidate collaboration signed to enable technology transfer for production of the Novavax COVID-19 vaccine in the Biologics Manufacturing Centre.

April to December 2021 – Technology transfer initiated and will continue in the coming months with engineering runs targeted for fall to demonstrate full-scale manufacturing in the environment under which the vaccine will be produced, including the facility, equipment and processes.

Early 2022 – Once engineering runs have been successfully completed, the Biologics Manufacturing Centre will produce process qualification batches to demonstrate consistent and reliable production of the vaccine using the established process under Good Manufacturing Practices (GMP) conditions.

These batches will be tested extensively to ensure the process has resulted in precisely the same quality in every batch, accepted by the vaccine sponsor, and can be approved by Health Canada for human use.

The results of these batches, with the supporting analysis and documentation, will then be submitted by the vaccine sponsor for regulatory approval by Health Canada. This is a complex process and can take several months.

CONTACT

Media Relations

[NRC.MediaRelations-RelationsMedias.CNRC@nrc-cnrc.gc.ca](mailto:MediaRelations-RelationsMedias.CNRC@nrc-cnrc.gc.ca)
media@novavax.com

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