200 Tech Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

Submission to the House of Commons Standing Committee on Foreign Affairs and International Development on its study of vaccine equity and intellectual property

April 29, 2022

Submitted by Moderna Biopharma Canada Corporation

moderna

200 Tech Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

MP Sven Spengemann
Chair of the House of Commons Standing Committee on Foreign Affairs and International Development

Regarding: Study on Vaccine Equity and Intellectual Property Rights

As President and General Manager for Moderna Canada and on behalf of our global team of scientists and researchers, I would like to thank you and the Committee for undertaking this study on vaccine equity and intellectual property rights.

Moderna's global public health strategy

We are pleased to take this opportunity to provide you with an update on the recent progress our company has made to support global health equity. We believe strongly that change is only possible when we take meaningful action and work together with our partners across government, health agencies, research organizations and other industry and not-for-profit entities.

Moderna also believes that we must all do more. For our part, we recently announced a new program directed at sharing our technology more broadly with the developing world, comprising three new initiatives aimed at advancing mRNA vaccines for the prevention of infectious diseases. First, Moderna announced a commitment to expand its global public health portfolio to 15 vaccine programs targeting priority pathogens[1] that threaten global health, advancing these vaccines into clinical studies by 2025. Moderna will prioritize development efforts against pathogens identified as persistent global health threats, including HIV, tuberculosis (TB) and malaria, neglected tropical diseases and the priority pathogens of the WHO and the CEPI. Second, to accelerate research with the aim of advancing additional vaccines, Moderna has launched a new program, mRNA Access, that will offer researchers use of Moderna's mRNA technology to explore new vaccines against emerging or neglected infectious disease. Third, Moderna has expanded its patent pledge to never enforce COVID-19 patents in the Gavi COVAX AMC for 92 low- and middle-income countries.

1. **Global public health portfolio**

Moderna has spent a decade refining its mRNA platform to accelerate the pace and success of mRNA medicines. The speed, scale and flexibility of this platform is uniquely suited for rapid response to Disease X. The Company's early clinical programs against Pandemic Influenza, Chikungunya and Zika represent a long-standing commitment to pandemic preparedness and global health.

The World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI) have issued calls to action to develop vaccines against priority pathogens that pose a threat to public health. Moderna's clinical portfolio already includes vaccines targeting COVID-19, HIV, Nipah and Zika. Moderna's expanded global health strategy will advance programs against the remaining pathogens by 2025. Moderna is also continuing its prototype vaccine approach, using preliminary versions of vaccines

[1] Moderna expects the 15 pathogens to include Chikungunya virus, COVID-19, Crimean-Congo haemorrhagic fever, Dengue, Ebola virus disease, HIV, Malaria, Marburg virus disease, Lassa fever, Middle East respiratory syndrome coronavirus (MERSCoV), Nipah and henipaviral diseases, Rift Valley fever, Severe fever with Thrombocytopenia syndrome, Tuberculosis, Zika

developed against representative viruses, which are rapidly adapted to tackle other related pathogens, in this way, preparing for Disease X[2]. The value of this prototype vaccine approach was demonstrated when early research on SARS-CoV-1 and MERS enabled Moderna's rapid response to SARS-CoV-2. Moderna is committing to continue research and early development toward pandemic preparedness through a prototype pathogen approach to creating vaccine libraries.

2. mRNA Access, powered by Moderna

To further expand the potential impact of mRNA vaccines, the mRNA Access program will open Moderna's preclinical manufacturing capabilities and research and development expertise to global partners, to together explore the possibility of mRNA to tackle the world's greatest global public health threats. Through the program, researchers at partnering institutions are invited to take advantage of Moderna's mRNA platform to develop mRNA medicines for existing neglected diseases. This program will leverage Moderna's Early Development Engine to accelerate vaccine development to the clinic and allow scientists around the world to explore novel vaccine designs against prototype viral families in preparation for Disease X. mRNA Access partners will work to accelerate innovation and enable new vaccines and medicines for emerging and neglected infectious diseases through collaborative research and preclinical development. We have recently announced that McGill University is the first Canadian University to be part of the mRNA Access Program.

3. Moderna's updated patent pledge

Moderna is undergoing a process of updating our patent pledge to never enforce patents for COVID-19 vaccines for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC).

To further underscore Moderna's commitment to low- and middle-income countries, and as part of the Company's continued support for achieving global health equity, Moderna is now updating its patent pledge to never enforce its patents for COVID-19 vaccines against manufacturers in or for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), provided that the manufactured vaccines are solely for use in the AMC 92 countries.

In non-AMC 92 countries, vaccine supply is no longer a barrier to access. In these countries, the Company expects those using Moderna-patented technologies will respect the Company's intellectual property. Moderna remains willing to license its technology for COVID-19 vaccines to manufacturers in these countries on commercially reasonable terms. Doing so enables Moderna to continue to invest in research to develop new vaccines, prepare for the next pandemic, and meet other pressing areas of unmet medical need.

Building capacity here in Canada and around the world

Over the past two years, Moderna has had the opportunity to work collaboratively with a number of government departments and agencies, including Health Canada, Global Affairs and the Public Health

[2] "Disease X" was named by the WHO to represent the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease. https://www.who.int/activities/prioritizing-diseases-for-research-anddevelopment-in-emergency-contexts

Agency of Canada, in working to protect Canadians from the Covid-19 pandemic. While these partnerships have successfully supported an unprecedented vaccination campaign and demonstrated remarkable efficiency and flexibility, Moderna also believes that there are indeed lessons to be learned from the Canadian and global pandemic experience.

Moderna very much agrees with the goal of emerging from the pandemic with improved access to innovative medicines. In our view, preparedness must include biomanufacturing in Canada and globally. Moderna is thrilled to be a part of new domestic capacity in Canada, with our announced partnership with the federal government. Over the next several years, Moderna will invest in a state-of-the-art manufacturing facility in Canada to produce mRNA vaccines in order to ensure a secure, reliable source of vaccines for the future, both for COVID-19 and beyond. This will, we hope, help Canada build a strong foundation of rapid pandemic response capabilities.

We also believe that this ability to increase surge capacity and ensure equitable access elsewhere in the world to support equitable access to treatments and vaccines is a goal we must collectively address. To this end, earlier in March, our company announced that we are building a state-of-the-art mRNA facility in Africa with the goal of producing up to 500 million doses of vaccines each year. Moderna anticipates investing up to $500 million in this new facility which will focus on drug substance manufacturing on the continent of Africa for the continent of Africa and could also be expanded to include fill/finish and packaging capabilities at the site. In parallel, Moderna is also working on plans to allow it to fill doses of its COVID-19 vaccine in Africa as early as next year.

We are committed to helping close the "last mile"

The Committee has also heard testimony relating to the challenge of vaccine distribution. We recognize that closing the "last mile" on the distribution of vaccines remains a significant hurdle to closing the access gap. While Moderna cannot solve this problem alone, we are open to working with those who are capable of producing a solution on the ground to help us ensure that doses are getting where they are needed. For our part, Moderna is pursuing a technological solution to closing the access gap, working on a next generation version of our COVID-19 vaccine, mRNA-1283, that will be refrigerator stable so that countries in the developing world do not need to maintain rigorous cold chain storage requirements that are needed for current mRNA vaccines.

In closing

Thank you again for this opportunity to brief the Committee on the actions that Moderna is taking to improve vaccine equity and intellectual property access globally. The work of your Committee is a vitally important part of better understanding both the issues at hand, and the actions Canada can take to continue its role as a global leader in improving public health.

Sincerely,

Patricia Gauthier

Patricia Gauthier, President and General Manager

Moderna Biopharma Canada

About Moderna

In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both ground-breaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic. In early 2020, Moderna began working on development of a SARS-CoV-2 vaccine and in 11 months, after demonstrating clinical safety and efficacy, Moderna's COVID-19 vaccine was authorized and hundreds of millions of people around the world have now received the vaccine. Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by *Science* for the past seven years.