AGREEMENT #3 CONCERNING THE COMMUNITY PHARMACY ACCESS PROGRAM FOR CERTAIN COVID-19 PHARMACEUTICAL TREATMENTS

BETWEEN

The MINISTER OF HEALTH, for and on behalf of the Government of Québec, whose business offices are located at 1075, chemin Sainte-Foy, Édifice Catherine-De Longpré, Québec (Québec), G1S 2M1, represented by Ms. Dominique Savoie, Deputy Minister;

hereinafter, the "Minister"

AND

The RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC, a legal person established under the Québec Health Insurance Act (CQLR, chapter R-5), having its headquarters at 1125, Grande Allée Ouest, Québec (Québec), G1S 1E7, represented by Marco Thibault, president and chief executive officer, duly authorized for the purposes hereof;

hereinafter the "Board"

WHEREAS, under Order in Council 318-2022 dated 16 March 2022, the Government of Québec entrusted the Board with the Community Pharmacy Access Program for Certain COVID-19 Pharmaceutical Treatments (hereinafter the "Program");

WHEREAS, under section 4 of the Program, the Minister and the Board may agree upon, by agreement, to amend the conditions listed in Schedule A and the list of pharmaceutical treatments in Schedule B, in particular to reflect the arrival on the Canadian market of new COVID-19 drug therapies and the recommendations made by the Institut national d'excellence en santé et en services sociaux;

WHEREAS, on 3 May 2022, the Minister and the Board signed the Agreement #1 in order to add a new pharmaceutical treatment to the Program, which agreement came into force on 9 May 2022;

WHEREAS, on 8 August 2022 came into force the Agreement #2 concerning the Community Pharmacy Access Program for Certain COVID-19 Pharmaceutical Treatments between the Minister and the Board in order to add a new unit format for Paxlovid™ (nirmatrelvir and ritonavir) to treat a person also suffering from kidney failure;

WHEREAS, on 20 October 2022, the Institut national d'excellence en santé et en services sociaux recommended to the Minister that the criteria for use and coverage of Evusheld™, and the maximum quantity of unit formats per service be amended;

WHEREAS, on 25 November 2022, the Institut national d'excellence en santé et en services sociaux recommended to the Minister that the criteria for the use of Paxlovid™ for the treatment of COVID-19 be amended;

WHEREAS it is expedient to further amend the Program to amend the criteria for use and coverage of Paxlovid™, Evusheld™, and the maximum quantity of unit formats per service of this pharmaceutical treatment for the treatment of COVID-19.

CONSEQUENTLY, THE PARTIES AGREE TO THE FOLLOWING:

1. Schedule A of the Community Pharmacy Access Program for Certain COVID-19 Pharmaceutical Treatments is replaced with the following:

"SCHEDULE A

For the purposes of this Schedule, severely immunocompromised includes persons who have:

- undergone a solid-organ transplant with immunosuppressive treatments or other disease treated with two immunosuppressants (e.g., antimetabolites + calcineurin inhibitors);

- anti-B cell therapy (monoclonal antibodies targeting CD19, CD20, CD22, CD30 and BAFF, e.g., ocrelizumab, rituximab, ofatumumab, alemtuzumab, obinutuzumab, blinatumomab, daratumumab, basiliximab, brentuximab, belimumab, anti-thymocyte globulins);

- chimeric antigen receptor (CAR) T-cell therapy or hematopoietic stem cell transplant until complete immune reconstitution;

- primary immunodeficiency on intravenous (IVIG) or subcutaneous (SCIG) non-specific human immunoglobulin replacement therapy (e.g., common variable immunodeficiency, combined immunodeficiency);

- active treatment for solid tumour or hematological cancer deemed highly immunosuppressive by the treating physician; some targeted biologic therapies are not considered immunosuppressive;

- untreated stage 3 or advanced human immunodeficiency virus infection or persons with acquired immunodeficiency syndrome (CD4 T cells count less than 200);

- an alkylating agent in the treatment of rheumatological disease (e.g., cyclophosphamide);

- treatment with a high dose corticosteroid (i.e., at least 20 mg/day of prednisone, or equivalent) for at least three weeks;

- any other condition that results in severe immunosuppression as deemed by the treating physician (e.g., certain untreated hematological or thymic neoplasia).

Are not considered as severe immunosuppressed and at very high risk of adverse outcomes, persons taking an immunomodulator (e.g., hydroxychloroquine) or a biotherapy directed against a specific inflammatory mediator or its receptor (such as TNFα, IL-1, IL-6, IL-17/23, integrins) as well as a Janus kinase inhibitor used as monotherapy or a corticosteroid therapy considered non-immunosuppressive or an antimetabolite monotherapy such as methotrexate or a combination of immunosuppressants for which the risk of COVID-19 complications is considered not significant (e.g., combination of

biotherapies directed against specific inflammatory mediators or their receptors, combination of methotrexate and biotherapy directed against a specific inflammatory mediator or its receptor).

Persons and health conditions eligible for the program

A) Paxlovid™ (nirmatrelvir and ritonavir):

For treatment of COVID-19, confirmed by nucleic acid amplification test (NAAT) or rapid antigen test, in persons who have been symptomatic for 5 days or less, do not require hospitalization, and fall into one of the following categories:

a) unvaccinated or partially vaccinated (incomplete primary vaccination) persons at high risk of COVID-19 complications due to any of the following conditions:

- persons aged 18 years and over with severe immunosuppression, regardless of vaccination status;

- persons aged 60 years and over;

- persons aged 18 years and over with at least one of the following conditions:
    - hemoglobinopathy
    - chronic renal failure
    - chronic hepatic failure
    - obesity (increased risk with BMI ≥ 35)
    - diabetes (increased risk if not controlled)
    - high blood pressure (increased risk if not controlled)
    - atherosclerotic cardiovascular disease
    - NYHA functional class II to IV heart failure
    - chronic pulmonary disease (e.g., COPD, moderate to severe asthma)

b) persons aged 18 and over with complete primary vaccination at high risk of complications, based on clinical judgment (e.g., very old age [70+] and/or multiple comorbidities and anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a last dose of vaccine received more than six months ago).

c) pregnant women with at least one of the risk factors listed below and an incomplete primary vaccination or anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a complete primary vaccination or a last dose of vaccine received more than six months ago, and after discussion with an experienced specialist or colleague:
    - severe immunosuppression
    - hemoglobinopathy
    - chronic renal failure
    - chronic hepatic failure
    - obesity (increased risk with BMI ≥ 35)
    - diabetes (increased risk if not controlled)
    - high blood pressure (increased risk if not controlled)
    - atherosclerotic cardiovascular disease
    - NYHA functional class II to IV heart failure

- chronic pulmonary disease (e.g., moderate to severe asthma)

d) youth weighing 40 kg or more with at least one of the risk factors listed below and incomplete primary vaccination or anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a complete primary vaccination or a last dose of vaccine received more than six months ago, and after discussion with an experienced specialist or colleague:

- severe immunosuppression
- hemoglobinopathy
- chronic renal failure
- chronic hepatic failure
- obesity (increased risk with BMI ≥ 35)
- diabetes (increased risk if not controlled)
- high blood pressure (increased risk if not controlled)
- atherosclerotic cardiovascular disease
- NYHA functional class II to IV heart failure
- chronic pulmonary disease (e.g., moderate to severe asthma)

B) Tixagevimab / cilgavimab (Evusheld™)

1. For pre-exposure prophylaxis of COVID-19 in:

a) persons aged 18 and over not infected with SARS-CoV-2, who have never received tixagevimab/cilgavimab (Evusheld™) for pre-exposure prophylaxis or have received it six months or more ago, if they meet the following criteria:

- severe immunosuppression, regardless of vaccination status, as deemed by the clinician if the last dose of COVID-19 vaccine was received 14 days ago or more;

- no COVID-19 vaccination or justified incomplete baseline vaccination and no alternative and at high risk of COVID-19 complications due to one of the following conditions:
  - aged 60 years and over;
  - with at least one of the following conditions:
    - hemoglobinopathy
    - chronic renal failure
    - chronic hepatic failure
    - obesity (increased risk with BMI ≥ 35)
    - diabetes (increased risk if not controlled)
    - high blood pressure (increased risk if not controlled)
    - atherosclerotic cardiovascular disease
    - NYHA functional class II to IV heart failure
    - chronic pulmonary disease (e.g., COPD, moderate to severe asthma)

b) pregnant women with at least one of the risk factors listed below and an incomplete primary vaccination or anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a complete primary vaccination or a last dose of vaccine

received more than six months ago, and after discussion with an experienced specialist or colleague:

- severe immunosuppression
- hemoglobinopathy
- chronic renal failure
- chronic hepatic failure
- obesity (increased risk with BMI ≥ 35)
- diabetes (increased risk if not controlled)
- high blood pressure (increased risk if not controlled)
- atherosclerotic cardiovascular disease
- NYHA functional class II to IV heart failure
- chronic pulmonary disease (e.g., COPD, moderate to severe asthma)

c) youth weighing 40 kg or more with at least one of the risk factors listed below and incomplete primary vaccination or anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a complete primary vaccination or a last dose of vaccine received more than six months ago, and after discussion with an experienced specialist or colleague:

- severe immunosuppression
- hemoglobinopathy
- chronic renal failure
- chronic hepatic failure
- obesity (increased risk with BMI ≥ 35)
- diabetes (increased risk if not controlled)
- high blood pressure (increased risk if not controlled)
- atherosclerotic cardiovascular disease
- NYHA functional class II to IV heart failure
- chronic pulmonary disease (e.g., COPD, moderate to severe asthma)

2. For early treatment of COVID-19

For treatment of COVID-19, confirmed by NAAT or rapid antigen test, in persons who have been symptomatic for 7 days or less, do not require hospitalization, and fall into one of the following categories:

a) unvaccinated or partially vaccinated (incomplete primary vaccination) persons at high risk of COVID-19 complications due to any of the following conditions:

- persons aged 18 years and over with severe immunosuppression, regardless of vaccination status;

- persons aged 60 years and over;

- persons aged 18 years and over with at least one of the following conditions:
    - hemoglobinopathy
    - chronic renal failure
    - chronic hepatic failure
    - obesity (increased risk with BMI ≥ 35)
    - diabetes (increased risk if not controlled)
    - high blood pressure (increased risk if not controlled)
    - atherosclerotic cardiovascular disease
    - NYHA functional class II to IV heart failure
    - chronic pulmonary disease (e.g., COPD, moderate to severe asthma)

b) persons aged 18 and over with complete primary vaccination at high risk of complications, based on clinical judgment (e.g., very old age [70+] and/or multiple comorbidities and anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a last dose of vaccine received more than six months ago).

c) pregnant women with at least one of the risk factors listed above and an incomplete primary vaccination or anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a complete primary vaccination or a last dose of vaccine received more than six months ago, and after discussion with an experienced specialist or colleague:
    - severe immunosuppression
    - hemoglobinopathy
    - chronic renal failure
    - chronic hepatic failure
    - obesity (increased risk with BMI ≥ 35)
    - diabetes (increased risk if not controlled)
    - high blood pressure (increased risk if not controlled)
    - atherosclerotic cardiovascular disease
    - NYHA functional class II to IV heart failure
    - chronic pulmonary disease (e.g., moderate to severe asthma)

d) youth weighing 40 kg or more with at least one of the risk factors listed below and incomplete primary vaccination or anticipation of suboptimal protection from hospitalization due to the circulating variant, despite a complete primary vaccination

or a last dose of vaccine received more than six months ago, and after discussion with an experienced specialist or colleague:

- severe immunosuppression
- hemoglobinopathy
- chronic renal failure
- chronic hepatic failure
- obesity (increased risk with BMI ≥ 35)
- diabetes (increased risk if not controlled)
- high blood pressure (increased risk if not controlled)
- atherosclerotic cardiovascular disease
- NYHA functional class II to IV heart failure
- chronic pulmonary disease (e.g., moderate to severe asthma).”.

2. Schedule B of that Program is amended by replacing the line on Evusheld™ (tixagevimab and cilgavimab) with the following:

“

Evusheld™ (tixagevimab and cilgavimab)	One package containing 150 mg of tixagevimab (100 mg/ml) and 150 ml of cilgavimab (100 mg/ml)	$1,000	2 units per service
	Supplies necessary for the administration of Evusheld™ *	$0.75	

**Only when the treatment is administered in a pharmacy*

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3. This agreement comes into effect on the date of the last signature.

IN WITNESS WHEREOF, the parties have signed this agreement, in duplicate, at the location and on the dates indicated below.

FOR THE MINISTER OF HEALTH:	**FOR THE RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC**:
At Québec,	At Québec,
on December 5, 2022	on December 5, 2022
Original signed	**Original signed**
_____	_____
Dominique Savoie Deputy Minister	Marco Thibault President and Chief Executive Officer