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168693
A/ADM: Michael Mills, 613-769-3738

Security: Normal

MEMORANDUM TO THE MINISTER

FOR DECISION

SUBJECT: Binding term sheet setting the initial terms for a future contract with Pfizer for its COVID-19 oral therapeutic drug

SUMMARY

This memorandum is to seek your approval to execute a binding term sheet with Pfizer Inc. and Pfizer Canada ULC to procure 1 million treatment courses of PF-07321332 with ritonavir (PAXLOVID in the U.S.) COVID-19 therapeutic on behalf of the Public Health Agency of Canada (PHAC). Canada will also have an option to procure up to an additional 500,000 treatment courses.

PAXLOVID is an oral therapeutic drug that is intended to treat COVID-19 patients with mild to moderate symptoms. Provinces and territories have indicated their interest for this product given its intended purpose in reducing hospitalization or death for those with COVID-19. As an oral solution, it will be easier to administer than other solutions that typically require IV infusion at hospitals or clinics.

Due to high global demand, Pfizer has proposed to execute a binding term sheet as the most efficient means to reserve an allocation of the product for Canada. The binding term sheet will establish the key terms and conditions that will be included in the final contract, to be signed.

Since this will limit the scope of future negotiations, your approval is being sought to execute the binding term sheet.

Once a final contract has been negotiated, your approval will be sought to award the contract under unlimited emergency authorities for the research, development, acquisition and deployment of medical countermeasures, including therapeutics related to COVID-19, Deliveries will not take place prior to Health Canada regulatory approval.

I recommend that you approve the attached binding term sheet (Annex A).

Canada

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TIME FRAME
A decision is requested at your earliest convenience.

BACKGROUND

The Government of Canada is taking steps so that Canadians have access to safe and effective COVID-19 therapies. These therapies are essential to saving lives, reducing suffering and alleviating the burden on health systems.

PHAC has already purchased several COVID-19 treatments, including sotrovimab by GSK, remdesivir by Gilead, tocilizumab and Regeneron by Hoffmann-La Roche, and bamlanivimab by Eli Lilly. All of these treatments require an IV administration at hospitals or clinics. PAXLOVID is an outpatient, oral antiviral COVID-19 therapy, making it easy to administer.

Pfizer filed its submission with the U.S. Food and Drug Administration on November 16, 2021, and also filed in Canada on December 1, 2021 with the view that it will target an approval date of February 28, 2022. Other countries such as the U.S., Australia, the United Kingdom and South Korea have already secured agreements to purchase this drug.

In order to execute a contract to procure this product, the proposed binding term sheet is first required, at Pfizer's request, to secure Canada's allocation of 1 million treatment courses of the product, and to establish the key terms and conditions that will form the basis of the final contract. It includes the price per treatment course, projected delivery schedule,

(Annex B outlines these provisions in more detail).

On November 12, 2021, the Deputy Minister's Procurement Committee for COVID-19 Vaccines and Therapeutics endorsed the procurement of this therapeutic.

ANALYSIS/CONSIDERATIONS

On November 5, 2021, Pfizer released positive interim data on its Phase 2/3 clinical trial where its investigational oral antiviral candidate was found to reduce the risk of hospitalization or death by 89 per cent in non-hospitalized high-risk adults with COVID-19, when treated within 3 days of symptom onset.

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As an oral solution, it is expected that demand for PAXLOVID will be high, since it will be easier to administer than traditional therapeutics that require IV infusion at hospitals or clinics.

The proposed binding term sheet is for a firm commitment of 1 million treatment courses plus options to purchase up to 500,000 additional treatment courses. The delivery schedule outlined in Annex B is dependent on Pfizer obtaining regulatory approvals by Q1-2022. Given the uncertainty of future demand requirements, Canada will have the ability to defer the delivery of doses into later 2022 or 2023, if mutually agreeable.

The price of per treatment course is consistent with the price being paid by other high-income countries purchasing similar volumes of this product.

Your emergency contracting authorities for the research, development, acquisition and deployment of medical countermeasures, including therapeutics related to COVID-19, are currently valid until December 31, 2021. We expect that these authorities will be extended beyond this date. However, if these authorities expire before the final contract is ready to be awarded, a separate Treasury Board submission could be required.

RISKS

Public Services and Procurement Canada assesses the risk of entering into this initial agreement with Pfizer as low.

The binding nature of the agreement requires both Canada and Pfizer to negotiate a contract incorporating these terms in good faith and using

PHAC has directed us to proceed based on the terms in the term sheet.

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RECOMMENDATION

I recommend that you approve the attached binding term sheet to enable the negotiation of a final contract with Pfizer.

Matthews, Bill Digitally signed by Matthews, Bill Date: 2021.12.02 12:32:33 -05'00'

Bill Matthews
Deputy Minister

December 2, 2021

I agree, Filomena Tassi

I disagree, Filomena Tassi

Attachments

- Annex A: Binding term sheet for Pfizer therapeutic (for signature)
- Annex B: Key terms

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EXECUTION COPY

BINDING TERM SHEET

Pfizer Inc. (**"Pfizer US"**) is currently in clinical development of Pfizer's proprietary orally administered SARS-CoV2 3CL protease inhibitor PF-07321332, that is co-packaged and co-administered with the pharmaceutical product ritonavir (together, the "**Product**").

Subject to clinical success, Pfizer US or its affiliate, Pfizer Canada ULC ("**Pfizer**"), anticipates potential approval from Health Canada as early as February 28, 2022 under the NDS-COVID submission pathway.

Her Majesty The Queen In Right of Canada, as represented by the Minister of Public Works and Government Services Canada ("**Government**") wishes to explore arrangements to secure Product supply for Canada during the pandemic period.

Government acknowledges and agrees that Pfizer US's efforts to develop and manufacture the Product are subject to significant risks and uncertainties. Notwithstanding the efforts and any estimated dates set forth in this Binding Term Sheet, the Parties recognize that the Product is currently in Phase 2/3 clinical trials and that, despite the efforts of Pfizer US in research, and development and manufacturing, the Product may not be successful due to technical, clinical, regulatory, manufacturing or other challenges or failures.

This Binding Term Sheet records the main terms between Pfizer US, Pfizer and Government in respect of the supply of the Product. The parties intend to enter into a more detailed definitive agreement (the "**Definitive Agreement**")

Further details of the legal effect of this document are set out below.

PARTIES	
Parties	(1) Pfizer Inc. ("**Pfizer US**"); (2) Pfizer Canada ULC ("**Pfizer**"); and (3) Her Majesty The Queen In Right of Canada, as represented by the Minister of Public Works and Government Services Canada ("**Government**").
PANDEMIC SUPPLY	
Authorization	In this Binding Term Sheet, "**Authorization**" means an authorization granted by Health Canada under Division 8 of the *Food and Drug Regulations* that allows the Product to be placed on the market in Canada. Pfizer will use its to obtain Authorization for the Product by February 28, 2022 ("**Target Authorization Date**"). Pfizer agrees to use to file for Authorization in Canada, on or around November 30, 2021.
Contract Period	The term of the Definitive Agreement shall commence on the date of execution thereof and shall end on the later of (i) December 31, 2023 and (ii) the final delivery of Product (**"Contract Period**").
Order & Delivery	Under and subject to terms to be agreed in the Definitive Agreement, Government will place a binding order (the "**Order**") for 1,000,000 courses of therapy (each being a five (5) day treatment course, "**Treatment Course**") of the Product (the "**Contracted Treatment Courses**"). Subject to points (i) to (vi) below, and as described further under the heading "Delivery Particulars" below, Pfizer will use to deliver the Order as follows (the "**Delivery Schedule**") provided that Authorization is received by the Target Authorization Date and the Definitive Agreement has been executed by such time periods: • Treatment Courses estimated to be shipped in Q1 of 2022 ("**Shipment 1**"); • Treatment Courses estimated to be shipped in Q2 of 2022, of which Treatment Courses to be shipped earlier in the quarter ("**Shipment 2**"); • Treatment Courses estimated to be shipped in Q3 of 2022 ("**Shipment 3**"); and • Treatment Courses estimated to be shipped in Q4 of 2022 ("**Shipment 4**"). The Parties agree that after Shipment 1 has been delivered, Government may defer, upon the mutual agreement of the Parties, the delivery of some or all of the remaining Contracted Treatment Courses to future dates within the

	Contract Period. If agreed, the Parties will establish a deferred delivery schedule for any deferred Contracted Treatment Courses. Pfizer confirms that each of the Contracted Treatment Courses to be delivered as part of Shipment 1 – Shipment 4 have been manufactured at a plant approved by Health Canada at the time of manufacture. (i) No Treatment Courses will be shipped prior to Pfizer receiving Authorization and prior to the execution of the Definitive Agreement. (ii) If Authorization is received after the Target Authorization Date, but before March 31, 2023, then the Delivery Schedule will shift accordingly and be adjusted to reflect the delay between the Target Authorization Date and the date of Authorization. (iii) (iv) (v) The Definitive Agreement will include the Product Shortages provision in Section 2.5 of the Vaccine Agreement. Government may request up to an additional 500,000 Treatment Courses to be delivered in Q4 2022 or later, subject to the following conditions: (a) the Product has received Authorization prior to such binding order being placed; (b) Pfizer has availability of supply of such additional requested Treatment Courses (the "**Additional Product**"); and (c) Pfizer agrees, in its sole discretion, to allocate the Additional Product to Government. Government acknowledges that the Product is novel and being produced under pandemic conditions, and despite the of Pfizer, Pfizer's efforts to develop, manufacture and supply the Product are aspirational in nature and subject to significant risks and uncertainties due to technical, clinical, regulatory and/or manufacturing challenges and/or failures. The Parties agree that Pfizer may, at its discretion, deliver Product with packaging and labelling in English only ("**Global Pack**"). The Parties acknowledge that if any customization of the Global Pack is required due to Canadian regulatory requirements, the Delivery Schedule will shift

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	accordingly and be adjusted to reflect the time necessary for Pfizer to meet such regulatory requirements.
PRICING	
Product Pricing	Pricing will be per Treatment Course. In total, the 1,000,000 Treatment Courses ordered comprising Shipments 1 – 4 will have an aggregate consideration of (the "**Total Cost**"). All pricing is exclusive of harmonized sales tax and inclusive of main carriage freight. The Total Cost is inclusive of transportation and delivery costs to the delivery centre(s) in Canada as nominated by Government and agreed by Pfizer. Government shall bear expenses for use of the Product in Canada.
Progress Payment	Government agrees to pay to Pfizer
Further payment terms	the remainder of the Total Cost (the "**Delivery Price**") is to be paid promptly to Pfizer upon delivery of the Contracted Treatment Courses.
OTHER PROVISIONS	
Liability protection	
Intellectual Property	The Definitive Agreement will include the No Other Warranty provision in Section 5.4 of the Vaccine Agreement, as well as the Intellectual Property provision in Article 7 of the Vaccine Agreement.
Other Terms	
Diversion Issues	The Definitive Agreement will include the Diversion Issues provision in Section 4.6 of the Vaccine Agreement.
Donations and resale	Except for further distribution in the jurisdiction permitted in accordance with the Definitive Agreement, Government shall not directly or indirectly resell, export, transfer, donate, exchange, swap, or otherwise distribute Product without Pfizer's prior written consent. To the extent the Contracted Treatment Courses supplied by Pfizer to Government constitute an excess of supply over

	the requirements of Government and there is an appropriate amount of shelf-life remaining on such excess Treatment Courses, Purchaser may, subject to the terms herein, conduct a total of 2 donations or resales (additional donations may be considered upon the mutual agreement of the Parties); provided that such donation or resale of Product shall be subject to and contingent upon Pfizer's prior written consent and contingent on receipt of: (i) (ii) written confirmation that Government and the receiving third-party countries or public institutions shall comply with applicable registrations, approvals, waivers, storage, transport, product acceptance requirements, destruction and disposal to the satisfaction of Pfizer in its sole discretion; and (iii) the exact quantity of requested Treatment Courses of Product for donation or resale, the related country and destination location(s) and the applicable batch number(s) and volume. If Pfizer permits such donation or resale in its sole discretion and in accordance with the terms set forth in the Definitive Agreement, Government shall promptly provide written notice to Pfizer to confirm the delivery of any authorized donated or resold Product, which shall specify the number of Treatment Courses per shipment of Product delivered, the applicable batch number(s), the delivery location and date of delivery. Additionally, to the extent that it is reasonably possible, Government shall be solely responsible for: (1) maintaining distribution data and detailed records with respect to any donation or resale and (2) upon reasonable request, supporting any Product recall or market withdrawal from the country or public institution receiving the Treatment Courses.
Announcements	The Parties consent to the issue of a press release, in the agreed form attached as Appendix A (the "**Agreed Press Release**"), promptly following execution of this Binding Term Sheet. Notwithstanding the foregoing, no Party shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of these terms, the wider transactions contemplated by it, or the relationship between the Parties, without the prior written consent of the other Parties (such consent not to be unreasonably withheld or delayed), except: a) as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction; or b) on terms that are consistent and do not go further than the matters covered in the Agreed Press Release. For clarity, unless consent is granted pursuant to this Announcements provision, no announcement or disclosure will include or infer the price per Treatment Course or indicative supply schedule.
Recall	The Definitive Agreement will include the Recalls provision in Section 4.7 of the Vaccine Agreement.
Information	Upon request, Pfizer shall keep Government apprised of the progress of (i) material developments of the Product that may, in Pfizer's reasonable opinion, significantly affect Pfizer's ability to meet its delivery schedule, (ii) clinical trials data and outcomes from these trials, and (iii) the extent to which Pfizer is on track to deliver the Order in accordance with the Delivery Schedule.
Legal Costs	Each Party will bear its own legal costs in preparing and concluding the Definitive Agreement.

EFFECT OF BINDING TERM SHEET	
Legal Effect of Binding Term Sheet	The parties identified at the end of this document expressly agree that all of the terms of this Binding Term Sheet are intended to be and are legally binding on the parties. If and solely to the extent that any court or tribunal of competent jurisdiction holds any provision of this Binding Term Sheet to be unenforceable in a final non-appealable order, such unenforceable provision shall be stricken and the remainder of this Binding Term Sheet shall not be affected thereby. In such event, the Parties shall in good faith attempt to replace any unenforceable provision of this Binding Term Sheet with a provision that is enforceable and that comes as close as possible to expressing the intention of the original provision.
Confidentiality	Each Party must not disclose any confidential information regarding this Binding Term Sheet or the Definitive Agreement to any third party, and must take all necessary steps to ensure that the confidentiality and security of such information is protected, except that a Party may disclose such confidential information: (a) after obtaining the written consent of the other Party (such consent not to be unreasonably withheld or delayed); (b) compelled to be disclosed pursuant to the *Access to Information Act*, R.S. 1985, c. A-1, provided however, if Government receives a request for disclosure or becomes legally compelled to disclose any confidential information in respect of Pfizer or its affiliates, prior to such disclosure Government will provide Pfizer with notice of the request and that disclosure may be or is required, as soon as reasonably possible given the circumstances, so that Pfizer or its affiliates at their discretion may seek one or more protective orders or other appropriate remedies; as required by an applicable law (including rules of stock exchange) after first providing at least 48 hours' notice to Pfizer about the form and content of the disclosure; (c) on a confidential basis to its employees, contractors or agents, and with respect to Government, its personnel and agents, and also includes individuals comprising the membership of Government's COVID-19 technical advisory groups, who: (i) are subject to an obligation of confidentiality protecting the confidential information on terms no less restrictive than those contained in this Binding Term Sheet; and (ii) have a need to know the confidential information in connection with this Binding Term Sheet and/or the Definitive Agreement. (d) where the information is already in the public domain other than through a breach of this Binding Term Sheet or any other obligation of confidentiality; or (e) in the case of Government, to a Canadian government agency to the extent necessary to enable the performance of its statutory functions. If a Party discloses any such confidential information pursuant to any of the above exceptions, it must ensure that all persons receiving such confidential information keep it confidential and do not disclose it except in accordance with the above exceptions. A Party must notify the other Party immediately after it becomes aware of any breach of this provision and must promptly take all reasonable steps

	to prevent or stop any breach if within its control.
Negotiation	The parties shall use acting in good faith, to execute the Definitive Agreement on or before from the date of execution of this Binding Term Sheet. Upon its execution by both parties, the Definitive Agreement will supersede and replace this Binding Term Sheet with immediate effect.
Governing Law, Jurisdiction and Dispute Resolution	The Definitive Agreement will include, and this Binding Term Sheet incorporates by reference, the Negotiations of Dispute provision in Section 12.1 of the Vaccine Agreement, as well as the Arbitration provision in Section 12.2 of the Vaccine Agreement.
Counterparts	This Binding Term Sheet may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Binding Term Sheet may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[Signature Page Follows]

SIGNED for and on behalf of
Pfizer Inc.

Name: Masum Hossain

Position: Regional President North America, Hospital Business Unit

Signature:

Date:

SIGNED for and on behalf of
Her Majesty The Queen In Right of Canada, as represented by the Minister of Public Works and Government Services Canada

Name: Filomena Tassi

Position: Minister of Public Services and Procurement

Signature:

Date: December 2, 2021

SIGNED for and on behalf of
Pfizer Canada ULC

Name: Cole Pinnow

Position: President

Signature:

Date:

SIGNED for and on behalf of
Pfizer Canada ULC

Name: Kevin Mohamed

Position: Canada Lead, Hospital Business Unit

Signature:

Date:

Appendix A
Agreed Press Release language

Pfizer to Provide Canada with 1 Million Courses of Investigational Oral Antiviral Candidate for COVID-19

- *First orally administered investigational protease inhibitor specifically designed to com bat COVID-19 being evaluated in clinical studies; currently undergoing Phase 2/3 safety and efficacy trials*
- *Courses are expected to be delivered through 2022, subject to Health Canada authorization*

Kirkland, QC, December xx, 2021 — Pfizer Canada today announced an agreement with the government of Canada to supply its investigational COVID-19 oral antiviral candidate, PF-07321332;ritonavir, subject to local regulatory authorization. PF-07321332 is the first orally administered investigational candidate evaluated in clinical trials that is spe cifically designed to combat COVID-19.

Under the terms of the agreement, the Government of Canada will acquire an initial quantity of one million treatment courses, to be delivered after regulatory authorization.

"We are honoured to work with the Government of Canada toward achieving our shared goal of addressing this public health crisis," said Kevin Mohamed, Canada Lead of Pfizer's Hospital Business Unit. "If successful, oral antiviral therapies such as protease inhibitors may help to reduce the severity or onset of illness in adults who contract, or have been exposed to, COVID-19. An oral treatment option may thus be an important tool to help address the ongoing global impact of the COVID-19 pandemic."

PF-07321332 is designed to block the activity of the main SARS-CoV-2 protease, an enzyme essential for viral replication. Co-administration with a low dose of ritonavir is expected to help slow the metabolism, or breakdown, of PF-07321332 in order for it to remain active in the body for longer periods of time at higher concentrations to help combat the virus. Ritonavir has been used extensively in combination with other antivirals to help slow metabolism in a similar way.

The EPIC (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19) Phase 2/3 development program for PF-07321332 consists of multiple ongoing clinical trials: one in SARS-CoV-2 infected adults who are at high risk of severe illness (including hospitalization or death), a second in infected, symptomatic adults who are at standard risk (i.e., do not have risk factors for severe illness), and a third aimed at preventing development of SARS-CoV-2 infections in adult household contacts of symptomatic COVID-19 patients.

About Pfizer Canada
Pfizer Canada ULC is the Canadian operation of Pfizer Inc., one of the world's leading biopharmaceutical companies. Our diversified healthcare portfolio includes some of the world's best known and most prescribed medicines and vaccines. We apply science and our global resources to improve the health and well-being of Canadians at every stage of life. Our commitment is reflected in everything we do, from our disease awareness initiatives to our community partnerships. To learn more about Pfizer Canada, visit pfizer.ca or you can follow us on LinkedIn, Facebook, Twitter or YouTube.

For more information:
Pfizer Canada Corporate Affairs
1-866-9-PFIZER (1 866 973-4937)
corporate.affairs.canada@pfizer.com

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s.20(1)(c) COMMERCIAL CONFIDENTIAL

2021-11-22

Pfizer PAXLOVID Oral Therapeutics– Summary of Key Terms

KEY TERMS	Pfizer (Binding Term Sheet) – Final Contract to be negotiated of signing Term Sheet
Committed number of doses	**2022: Total of 1M treatment courses**
Regulatory Approval	Pfizer will use to submit its filing to Health Canada on or around 30 November 2021 and will target 28 February 2022 as the regulatory approval date.
Deferral Rights	With the **consent of Pfizer**, Canada may defer the delivery of treatment courses, after the Q1 shipment during the contract period up to Dec 31, 2023.
Delivery Schedule for committed purchase	**2022 Supply of 1 million treatment courses** • to be shipped in Q1 of 2022* • to be shipped in Q2 of 2022** • to be shipped in Q3 of 2022 • to be shipped in Q4 of 2022 *of these treatment courses to be shipped earlier in the quarter* Pfizer will use its to obtain Authorization for the Product by February 28, 2022. If Authorization is received after the Target Authorization Date, but before 31 March 2023, then the Delivery Schedule will shift accordingly and be adjusted to reflect the delay between the Target Authorization Date and the date of Authorization.
Options	**2022/2023**: Up to 500,000 additional treatment courses, at **Pfizer's sole discretion** which would be subject to available supply and delivered in Q4-2022 or later.
Cost	per treatment course Total of up to for the firm commitment of one million initial treatment courses. Total contract value if all options are exercised of up to
Distribution/ Storage	The estimated shelf-life for this product is currently assessed at 12 to 18 months. The final shelf-life will depend on the regulatory approval. Pfizer will agree to store unused doses.

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KEY TERMS	Pfizer (Binding Term Sheet) – Final Contract to be negotiated of signing Term Sheet
Financial Risks / Payment terms	
Right to Sell/Right to donate	The APA provides for **two** donations/resale of treatment courses that are considered excess requirements. Additional donations/resales could be allowed with **Pfizer's consent**. Pfizer's prior written consent and Indemnification will apply to donated or resale product.
Indemnification	
Limitation of Liability	