Dr. Albert Bourla
Chairman of the Board
Chief Executive Officer

Pfizer Inc
235 East 42nd Street, New York, NY 10017-5755

December 23, 2021

Ms. Beatriz Balbin
Chief
Special procedures Branch
OHCHR Ref: OL OTH 225/2021
(email to sylvain.lidome@un.org)

Pfizer's response to joint communication from the Working Group on the issue of human rights and transnational corporations and other business enterprises; Special Rapporteur on the right to development; Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; Independent Expert on the promotion of a democratic and equitable international order; Independent Expert on human rights and international solidarity and Special Rapporteur on extreme poverty and human rights

Your Excellencies,

Thank you for the opportunity to communicate with the distinguished independent human rights experts. I am pleased to share with you details about Pfizer's priorities and work to respond to the COVID-19 pandemic and our commitment to respect human rights. We agree on the utmost relevance that human rights have to the healthcare sector, given the right to health's wide-ranging interconnections to other fundamental rights.

Pfizer's purpose – Breakthroughs that change patients' lives – fuels everything we do and reflects both our passion for science and our commitment to patients. We know that our COVID-19 vaccine has the potential to change more lives than any other breakthrough from the past century and are aware this comes with a responsibility towards ensuring access.

We are extremely concerned about the toll that COVID-19 is taking on the lives and well-being of people all over the world. This is why we have put all the power of our Company behind the objective of contributing to ending this pandemic.

But we knew that no one company, vaccine or treatment would be enough and that we would need to harness the potential of the full biotechnology ecosystem. That is why, in March last year, we committed to sharing our scientific tools and insights, development expertise, and manufacturing

capacity in our 5-Point Plan[1]. We also stood in solidarity with industry leaders and pledged to protect scientific integrity, building on our rich history in vaccine research and development. Pfizer made a public pledge—along with eight other vaccine makers—to help protect the time-tested scientific processes and regulatory protocols that have helped guide the safe delivery of medicines and vaccines to address patients' unmet needs. Pfizer has also committed to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)'s five steps to advance vaccine equity and the Life Sciences Companies and Bill & Melinda Gates Foundation's Commitments to expand access to COVID-19 diagnostics, therapeutics and vaccines.

One year later, there is increasing hope that the world will help defeat the COVID-19 pandemic thanks to the outcomes of these unprecedented mobilization and collaborations, including the one we launched with our partner BioNTech that enabled development of the Pfizer/BioNTech COVID-19 vaccine.

Our approach to human rights and due diligence

Our COVID-19 efforts have not happened in isolation. In recent years Pfizer has been engaged in a review of the UN Guiding Principles on Business and Human Rights and what they mean for our business. After assessing with internal and external stakeholders, we concluded that we needed to firmly state that the right to health is the most salient human rights issue for Pfizer and that more work was needed to demonstrate the steps the company is taking to bring a human rights-based approach to our work. This resulted in publishing our human rights policy statement, which builds upon our purpose, breakthroughs that change patients' lives, and reflects our commitment to equity, which is one of the four core values[2] that define our company and culture.

Human rights risks associated with Pfizer/BioNTech's COVID-19 vaccine are no different to those of other Pfizer products; the pandemic situation, however, has exacerbated them. The right to health remains our most salient risk, with availability, accessibility and affordability standing as key areas of focus. We knew that minority populations and those in hard-to-reach locations, or lacking access to basic health services, would be those whose right to health would be most severely impacted during the pandemic.

Since the beginning of the pandemic, our paramount consideration has been equitable and affordable access to COVID-19 vaccines for all people around the world. With the most vulnerable in mind, we opted for a multi-pronged approach to enable this access:

First, we chose to use a tiered pricing approach that was set based on the income level of each country which allowed Governments to ensure that there is little to no out-of-pocket costs for their populations;

Second, we partnered with global health stakeholders to help strengthen healthcare systems where greater support may be needed to deploy COVID-19 vaccines; and,

Third, we continued investing in innovation to enable access, advancing research into the needs of specific populations and into the evolution of the disease.

[1] For details on how we have been delivering against our commitments visit this link: Coronavirus disease (COVID-19) Facts, News & Information | Pfizer

[2] Pfizer's core values are Equity, Courage, Joy and Excellence.

Not-for-profit pricing and volume commitments for low income and lower-middle income countries

Early in our development program (June 2020), we decided to offer our vaccine through tiered pricing. During the pandemic we chose to charge governments a price that help them ensure that there is little to no out-of-pocket costs for their populations. And recognizing that equity doesn't mean we give everyone the same, but rather we give more help to those in higher need. We set a lower price for middle-income than high-income countries, and we are providing the vaccine to low-income and lower-middle-income countries at a not-for-profit price.

From day one of our vaccine development program, our outreach has been broad and inclusive to help ensure equitable access. We approached all governments where Pfizer has a presence and global health organizations in parallel, including COVAX.

Early on the majority of our first doses were reserved by the high-income countries because middle- and low-income countries had placed orders first with other vaccine makers, either because of the uncertainty of mRNA technology or because they were pursuing other options. Because of some of the challenges faced by other vaccine producers, many of these countries later came back to us and we worked to rapidly establish agreements and allocate doses as quickly as possible. Our contractual obligations on vaccine allocations have been determined by this sequence of events.

To date, we have supplied more than 2.5 billion doses of the Pfizer-BioNTech COVID-19 vaccine to 165 countries in every region of the world. Of these, more than 871 million doses have been delivered to 97 low- and middle-income countries. Specifically,

- We are a proud partner to COVAX, with an agreement to supply 40M doses in 2021 in alignment with their allocation strategy for the Pfizer-BioNTech vaccine.
- In July this year we signed a milestone agreement with the US Government to provide 1 billion vaccines doses that they would subsequently donate to COVAX's AMC 92 and African Union Countries in 2021 and 2022. The first shipment from the US Government agreement reached Rwanda on August 18, 2021. As of December 19, 2021, more than 170 million doses have been delivered to 56 low-and-lower-middle income countries as part of this specific program[3].
- Similarly, we are also supporting the European Commission and participating member states in their efforts to provide donations to countries in need through COVAX. Pfizer/BioNTech, the European Commission and COVAX have established a framework that enables EC member states to donate doses from their allocations to low- and lower-middle-income countries in need through COVAX, with France acting as the coordinating member state for donations. The first donation under this framework, which occurred in late October, was the donation of doses from France to Rwanda. As of December 12, 2021, more than 7.4 million doses have been donated by EU nations to countries in need.

Because of all these ongoing initiatives and our continued efforts to boost vaccine manufacturing, we have pledged to supply 2 billion doses to low-and middle-income countries through 2022 – 1 billion each year. Our current allocation to low- and middle-income countries from all supply pathways[4]

[3] More information about status of vaccine deliveries via this donation program can be accessed via USAID's website.

[4] Our current supply pathways include direct supply agreements with country governments, supply agreements with supranational organizations like COVAX and the European Union, partnerships with wealthy nations to donate doses to countries in need and humanitarian donations to vulnerable populations

which includes also bilateral agreements and the initiatives mentioned above, has already surpassed this pledge in 2021 with over 1.1 billion doses contracted.

We recognize and are concerned by the relative lower pace with which vaccines ended up reaching low-income countries, however, it is important to also acknowledge that approximately two thirds of the 1.3 billion people living in poverty are in the middle-income countries. Nonetheless, we anticipate that there will be a substantial increase in Pfizer/BioNTech vaccine shipments through the end of the year with a particular focus on low- and lower-middle-income countries that are further from global targets.

Capacity and resources to strengthen vaccine access for LMICs

We recognize the dire need for vaccines in low-income country populations. We continue to see reliable vaccine deliveries to those countries as a central part of Pfizer's COVID-19 response and are continually working to improve the efficacy and speed of delivery to their vulnerable populations.

We've worked to leverage our expertise to both expand and improve the supply network and storage and handling requirements of the vaccine itself – to meet the needs of our global network. We remain on track to produce 3 billion doses this year – more than double our original 1.3 billion-dose estimate for 2021, of which at least 1 billion will go to low- and middle-income countries, as mentioned above. Pfizer expects to manufacture 4 billion doses in 2022.

Many elements have been critical to achieving this increase, including bringing on additional Pfizer and BioNTech facilities and external suppliers, expanding the supply of raw materials, and enhancing the manufacturing process itself. We have reduced our COVID-19 vaccine manufacturing timeline from approximately 110 days – from start to vial-ready – to an average of 60 days, an almost 50% improvement.

We have continued to invest and have made changes to the formulation of the current vaccine to make it more stable and easier to use, important elements impacting accessibility in low- and middle-income countries. The shelf life has been extended to 9 months and the vaccine can now be stored in a standard refrigerator for up to 31 days after being removed from our innovative thermal shipper.

But we know that global vaccination targets can be achieved, and people's rights to health fulfilled, only with support from *all* global health stakeholders, including vaccine manufacturers. Such partnership is of utmost importance to ensure country readiness and absorption of vaccines, as these are the access challenges requiring the most attention today.

Distributing these types of products rapidly and at national scale has no precedent in modern public health, and close coordination across all stakeholders is critical to the success of vaccination campaigns. Some of the country readiness challenges we are facing today include acceptance by the country's regulatory body, confirmation that the country can meet product handling requirements, the availability of sufficient ultra-cold-chain (UCC) and/or traditional cold chain capacity for both the vaccine and diluent, basic supplies such as syringes, and the development of a delivery strategy to reach target populations. Without cold chain support countries are not able to accept high volumes of vaccine that allow for robust vaccination campaigns. And without service delivery and sufficient workforce capacity, vaccines in country will not result in vaccinations. *These elements demonstrate that to achieve equitable access, it is not just vaccines that will bring an end to the pandemic, but vaccinations.*

At the time of writing, we are on pace to ship 43 million doses to the 8 southern African countries on the recently enacted Omicron travel ban lists by year end. For 5 of the 8 countries, Pfizer has been asked by their respective governments over the past several months to delay or pause shipments due to issues related to country readiness.

Therefore, greater investment in readiness efforts in many lower income countries will still be necessary to ensure that vaccines shipped effectively reach populations. The COVAX Facility and its international health partners have played a key role to support country readiness for vaccines, and Pfizer is committed to providing our expertise and resources to strengthen healthcare systems where greater support may be needed.

Therefore, Pfizer is partnering with global health stakeholders, including COVAX, to analyze supply chain capabilities in low-income countries to understand where the private sector can lend expertise and support the delivery of any COVID-19 vaccine - including dry ice supply, transportation, and best practice sharing. As a few key examples:

- Pfizer and the UPS Foundation are committed to accelerating the equitable distribution of COVID-19 vaccinations. The UPS Foundation is donating freezers to countries that need assistance with building out their ultra-cold chain capacity, and Pfizer provides guidance and experience in product supply. Our partnership leverages innovation in the healthcare cold chain to truly move our world forward by safely, securely and quickly delivering highly sensitive, critically needed vaccines to areas where they are needed most.
- As part of a four-year partnership with Zipline, Pfizer is supporting an innovative pilot initiative in Ghana, focused on delivering vaccines requiring cold-chain storage to hard-to-reach areas using drones. The initial success of the project suggests that the program could be quickly expanded to deliver doses of COVID-19 vaccines to remote regions across the world where Zipline operates.
- Pfizer has signed an MOU with Global Environment and Technology Foundation to collaborate with Project Last Mile. The partnership is focused on aligning the supply chain expertise and technical capabilities of Coca-Cola, a company whose supply chain is characterized as one of the widest reaching in the world, with technical expertise from Pfizer on vaccine handling, storage and administration in order to improve the availability of vaccines in developing countries, and, in particular, to those residing in and around the last mile of the medical supply chain in Africa.

We are also drawing on our lessons learned from the last two years to address existing challenges with vaccine delivery. For example, internally we are exploring new strategies to improve the global COVID-19 vaccine delivery system, from supply chain through distribution, and better country readiness challenges.

Addressing access complexities from trade & regulatory policies

Export restrictions, regulatory needs, and border measures have all had an impact in our ability to manufacture and distribute vaccines. As we bring additional partners into our supply chain, the risk that trade bottlenecks will delay vaccine distribution increases significantly. Export restrictions for COVID-19 vaccines created cost and uncertainty and introduced additional access challenges for low and lower middle-income countries participating in the COVAX Facility.

Initiatives to reduce or eliminate export restrictions, today and in future, will be critical. The Trade and Health Initiative (TAHI) sponsored by over 50 WTO members is a welcome step in that direction.

Similarly, a strong partnership between industry and regulatory agencies is helping to expedite the delivery of lifesaving medicines and vaccines to patients.

Pfizer has worked closely with the leaders of the World Trade Organization, World Health Organization, World Bank, and International Monetary Fund to identify very concrete steps that these organizations, in partnership with member governments, can take to address these challenges in the near term[5]. We are committed to continue supporting this endeavour.

Complementing our equitable access strategy with targeted donations in humanitarian settings

We recognize that we have a fundamental corporate responsibility to respect human rights by working to prevent adverse impacts on people from our operations and business relationships. At the same time, we see an important role for strategic philanthropic donations of our products in high-risk settings where other avenues are not necessarily a viable option. These donations do not replace our efforts to ensure equitable access to health, but rather complement them.

Pfizer and The Pfizer Foundation[6] have a long history of addressing humanitarian disasters. Since the beginning of the pandemic, we have been working with governments and international non-governmental organizations to provide relief and support where it is needed through donations of much needed medications and by working to support front line health workers in vulnerable communities.

- The Pfizer Foundation[6] provided $30 million in grants to help meet front line needs during the pandemic. Our donations have reached 165+ partners worldwide to help these organization address the pandemic and strengthen healthcare systems, so they are better prepared for the next global health emergency.
  - Grants to the International Rescue Committee (IRC) supported their COVID-19 emergency response in East Africa, as well as longer term support to strengthen health systems and improve access to primary care for refugees in Jordan.
  - Grants to UNHCR supported their work to strengthen critical health, protection, and outreach measures in response to COVID-19 for refugee populations in Colombia and Bangladesh. With this grant funding, UNHCR is leading critical health programs, which have the potential to impact approximately 1.7 million refugees in Colombia and 870,000 refugees in Bangladesh.
- To support the surge in infection and hospitalization in India, last Spring we mobilized the largest humanitarian relief effort in our company's history donating more than $70 million in medicines used as part of the country's treatment protocol so that every COVID-19 patient in every public hospital across the country can have access to the Pfizer medicines they need free of charge for a three-month period. This effort, in combination with Pfizer Foundation funding that supported humanitarian organizations providing essential and life-saving equipment to India, such as ventilators, oxygen concentrators and consumables, was our largest and most comprehensive humanitarian relief response ever. We are also in active discussions with partners and global health experts to determine where targeted humanitarian donation programs for a COVID-19 vaccine are needed for the most vulnerable populations. Currently, Pfizer/BioNTech's Covid-19 Vaccine is not approved in India.

[5] See global_race_infographic_e.pdf (wto.org)

[6] The Pfizer Foundation is a charitable organization established by Pfizer Inc. It is a separate legal entity from Pfizer Inc. with distinct legal restrictions.

- As part of a collaboration with the Jordanian Ministry of Health and United Nations High Commissioner for Refugees (UNHCR), Pfizer has agreed to donate back to the country a portion of the doses administered to refugees from its national supply. This allows Jordan to effectively and efficiently manage a national vaccination program to reach its population while ensuring that additional support is provided to protect the most vulnerable. In August 2021, Pfizer/BioNTech provided the first shipment of 150,000 donated doses to Jordan to replace the doses already administered to refugees. Additional shipments will follow.
- As part of the companies' collaboration with Lebanon's Ministry of Health and UNHCR, Pfizer-BioNTech will also be donating a total of 600,000 vaccine doses to Lebanon to replace doses administered to refugees. The first shipment with 100,000 doses reached the country during the week of September 12, 2021. The remaining doses will be delivered in the fourth quarter of 2021.

Prioritizing at-risk people and continued innovation to address inequity and enable access

We have worked relentlessly to leverage our decades of experience and expertise in development, testing, manufacturing and distribution along with our partnerships to provide a safe and effective vaccine for *countries all over the world that want it*. We have put in place direct supply agreements with country governments, supply agreements with supranational organizations like COVAX and the European Union, and agreements with wealthy nations to donate doses to countries in need and humanitarian donations.

From the start, we committed to decreasing health disparities in underrepresented populations through our clinical trials. In our landmark COVID-19 vaccine trial, we selected investigative sites in diverse communities in the United States and globally that were disproportionately affected by COVID-19, to help ensure that individuals in communities that have been most impacted had the opportunity to participate. In our landmark Phase 3 study, approximately 42% of overall and 30% of U.S. participants came from diverse backgrounds. We shared with our investigative sites the importance of recruiting individuals who fully represent the racial and ethnic diversity of their communities, and we engaged patient advocacy partners and community groups to raise awareness about the importance of participation and representation. Our commitment is to design clinical trials so that enrollment can reflect the racial and ethnic diversity of countries where we conduct them.

Immediately upon the read-out of our efficacy analysis of the Phase 3 clinical study with the confirmation that our vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints and that and it was well tolerated, with no serious safety concerns observed, we began submitting applications to regulatory agencies in countries all around the world, including in low- and middle-income countries and with WHO for Emergency Use Listing (EUL) -we knew the latter would play a critical role in advancing access.

The Pfizer-BioNTech vaccine was granted an EUL by the World Health Organization on December 31, 2020. On January 8, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) published its recommendations for the Pfizer-BioNTech vaccine.

We continue to study the safety and efficacy of the vaccine. Specifically, we continue advancing the science and knowledge about the impact of our COVID-19 vaccine in specific populations, such as pregnant women and children. We have obtained approval for new storage options to help address distribution challenges, and we are delivering on our commitment to advance our research program

for a COVID-19 Antiviral treatment –which remains subject to regulatory approval and already has shown encouraging results.

Pfizer's position on sharing of intellectual property, technology, and know-how

The pandemic has highlighted the extraordinary value that a vibrant private sector can deliver to society. It took significant investments, at-risk, to bring diagnostics, treatments and vaccines to tackle COVID-19.

We understand there are diverging views about the relationship between intellectual property (IP), access to vaccines, and human rights; we would like to provide further clarification of our views. We believe that the IP system is an essential facilitator of access to vaccines around the world and that IP protections support the right to health by encouraging investment in needed medical innovation. As reflected in the 'IP Principles for Advancing Cures and Therapies' (IP PACT), we are committed to patient and societal benefit as guiding principles in our IP practice. Responsible use of our IP enables us to engage in collaborations and partnerships that have the potential to speed up progress on the most pressing unmet medical needs, including COVID-19.

The incentives provided by the IP system enable the creation of the expertise and infrastructure that is required to tackle the worst diseases of our time, including the COVID-19 pandemic. Due to the legal certainty provided by the IP system, the collaborations needed to ensure the early introduction of new vaccines across different markets became possible—our collaboration with BioNTech is one such example. New treatments and vaccines, such as Pfizer-BioNTech's COVID-19 vaccine, as well as improvements to existing medicines, are made possible because advancements in science are incentivized, valued, and protected by way of intellectual property rights. Additionally, the unprecedented scale up of manufacturing, supported also by voluntary licensing and partnerships with Contract Manufacturing Organizations (CMOs), would not have been possible without the existing IP framework: globally, to date, companies have signed 335 manufacturing and production agreements to share manufacturing know-how and scale up production of COVID-19 vaccines, and 116 agreements for production of COVID-19 therapeutics.

We are fully committed to efforts to promote access to medicines and vaccines throughout the world and will continue to carefully evaluate and consider all reasonable options and mechanisms to ensure that the COVID-19 vaccine and any potential therapies to help address the pandemic are accessible to those who need it.

Pfizer shares the goal of facilitating access to medicines for patients and we support implementation of the Doha Declaration, which recognizes countries' right to protect public health, while also acknowledging that IP protection is important for the development of new medicines. We understand that the limited, narrow use of a compulsory license to address a national health emergency may be appropriate under certain circumstances and if all other options have been exhausted. We remain committed to working directly with governments and other stakeholders, including to help ensure the vaccine and any potential treatment developed by Pfizer to address COVID-19 is accessible and affordable for those who need them. We recognize the unique level of economic development and social challenges of Least Developed Countries (LDCs), as defined by the United Nations Committee for Development Policy, and therefore Pfizer has a general policy of patent non-enforcement in LDCs.

As mentioned above, experience has demonstrated that the challenges to ensuring equitable distribution of the COVID-19 vaccine stem not from the IP system but rather from systemic and policy challenges such as tight supplies for vaccine manufacturing, export controls and other trade barriers

affecting both vaccine manufacturing supplies and final product (which also affected products in our non-COVID lifesaving portfolio), and distribution infrastructure limitations that determine country readiness, including cold chain capacity, availability of syringes and diluents, vaccine hesitancy, etc. Weakening or waiving IP rights would not address these real-world challenges in the short term, nor will it contribute to better future pandemic preparedness and response.

Intellectual property as an enabler for access

We are fully aligned with the overarching imperative of increasing overall supply to achieve equitable access. Since the beginning of our vaccine development program, we have focused our efforts and resources in ways that maximize our supply so we can support the global need. Because of the urgent need to vaccinate more people, we are continuously exploring innovative ways to increase the number of doses we're able to supply – which includes expanding our existing facilities, adding more suppliers, and bringing on additional Pfizer/BioNTech sites and contract manufacturers around the world to produce the vaccine.

Pfizer and BioNTech's global COVID-19 vaccine supply chain and manufacturing network now spans four continents and include more than 20 manufacturing facilities, including contract manufacturing agreements that Pfizer has in place to further accelerate access around the world. Last July we announced a landmark agreement with The Biovac Institute in South Africa to manufacture the Pfizer-BioNTech COVID-19 vaccine exclusively for the 55 member states that make up the African Union, and in August, Pfizer and BioNTech also announced the signing of a letter of intent with Eurofarma Laboratórios SA, a Brazilian biopharmaceutical company, to manufacture our COVID-19 vaccine for distribution within Latin America.

Such efforts are facilitated by the IP framework that protects the innovation and allows for secure transfer of technical knowledge. We will continue to explore and pursue opportunities to bring new partners into our supply chain network to further accelerate access to the COVID vaccine.

To further explain our position, it is important to understand that vaccine manufacturing is a biological production. It is extraordinarily complex under any circumstances, and even more so during a pandemic. The steps involved in a technology transfer include – but are not limited to – on-site development, equipment installation, engineering and process qualification tests, and regulatory approvals. The timeline for technology transfers is dependent on the extent of work needed during the transfer. On an average a fill/finish technology transfer (where product is filled into vials/syringes and packaged for delivery) takes anywhere from 18 months to three years from project kickoff to the qualification tests in which the new facility demonstrates that it can consistently execute a well-controlled process and make quality product (also known as performance qualification (PPQ) execution).

Expanding vaccine manufacturing to organizations without a proven track record and without the necessary skills, experience, or expertise to reliably source and manufacture vaccines could result in failures, which would put pressure on raw resources, potentially diverting them away from manufacturers who are producing COVID-19 vaccines and other essential vaccines to protect against a wide range of diseases. Lapses in quality could result in loss of trust in our processes or our ability to deliver a high-quality vaccine.

Enabling access to our COVID-19 treatment candidate (PF-07321332)

We believe that antivirals could play an important role in treating or preventing COVID-19, complementing vaccines and other therapeutic and social interventions. This is why we have been working diligently to actively leverage our deep heritage in anti-infective development, as well as our research, scale, and capital resources, to create targeted treatments that may help those who contract the virus around the world. We know that these efforts will only be truly impactful if they can reach those most in need.

Aligned with our belief that the current innovation system is an enabler of access, Pfizer and the Medicines Patent Pool (MPP) recently announced a voluntary licensing agreement for Pfizer's COVID-19 oral antiviral treatment candidate PF-07321332 in low- and middle-income countries. Licensing antiviral intellectual property to the MPP potentially helps to enable Pfizer's investigational oral antiviral, if authorized or approved, to reach low-income and lower-middle-income countries as well as some upper-middle income countries, accounting for approximately 53% of the world's population. Pfizer will not receive royalties on sales in low-income countries and will further waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

Our access strategy aims at delivering safe and effective antiviral therapeutics as soon as possible and at an affordable price. In addition to our agreement with the MPP, during the pandemic Pfizer will offer our investigational oral antiviral therapy, if authorized or approved, through a tiered pricing approach based on the income level of each country to promote equity of access across the globe. High and upper-middle income countries will pay more than lower income countries, which will pay a not-for-profit price.

Pfizer has also begun and will continue to invest up to approximately $1 billion to support the manufacturing and distribution of this investigational treatment candidate, including exploring potential contract manufacturing options. We have initiated bilateral outreach to countries in all regions around the world, as well as to supranational organizations, to ensure no one is left behind.

We have also been leveraging lessons learned from the development and distribution of the vaccine—including challenges faced by manufacturers, governments and the broader global community—to inform a strengthened approach to ensuring access.

Pfizer's policies regarding liability, indemnification, and transparency

The speed and scale of the pandemic response creates a risk of unprecedented liability exposure for all persons involved in the development, production and use of the vaccine, including doctors, pharmacies, NGOs and manufacturers. Appropriate liability protections are critical for all those working to develop and distribute the vaccine.

The urgency of this crisis has required pharmaceutical companies around the world to work to develop vaccines on an expedited basis and rapidly scale up production to provide for distribution to billions of people in record time. Governments around the world understandably want access to vaccines as quickly as possible, but these circumstances create unusual and unprecedented risks to vaccine manufacturers of substantial legal claims across the globe. This is why Pfizer seeks indemnity and liability protection in all agreements, including through the COVAX Facility, consistent with applicable local laws.

Many governments around the world do not have the legal or legislative protections in place for vaccine manufacturers that are already in effect in the United States. Thus, in supply contracts with all governments around the world, Pfizer asks that the government indemnify Pfizer, BioNTech, their contractors and suppliers, and others involved in the development or manufacture of the vaccine against claims by third parties alleging an injury relating to the vaccine, in order to achieve a similar level of protection as afforded by the U.S. PREP Act. To ensure the indemnity is enforceable against the governments, the governments have agreed to waive sovereign immunity from claims.

We have demonstrated transparency throughout the vaccine development process and in engagements with governments. It started with our commitment to openly sharing the details of our clinical trial program and publishing data at the earliest opportunity in peer reviewed journals. We have throughout the process worked to provide as much information as we are able as to when we expect to meet manufacturing targets, sharing this critical information with the public to help governments and individuals manage expectations and logistics.

We have worked with governments around the world to balance our efforts to be transparent with local laws, and the need to keep certain details of our contracts confidential, as is customary in commercial transactions, so as not to prejudice the parties or ongoing negotiations around the world. Freedom of Information or Right of Information Laws provide a mechanism for interested parties to seek certain information from governments, and Pfizer cooperates with governments when they receive such inquiries, consistent with those countries' laws.

We recognize that transparency is a key enabler of the right to health and equitable access, and we are committed to continually exploring how we can further share information with our stakeholders. The outreach and requests for information about our vaccine access approach that we have received from governments, international institutions and civil society have been extremely valuable to us, sparking internal conversations on ways to continue evolving Pfizer's approach to transparency.

Quality and safety

Pfizer has an unwavering commitment to keeping high standards of safety, quality, and compliance at the forefront of all we do. We are a proven, reliable multinational vaccine producer, supplying vaccines to more than 165 countries. Before the Pfizer-BioNTech COVID-19 vaccine was developed, Pfizer manufactured more than 200 million doses of other Pfizer vaccines annually. We are also one of the largest sterile injectables suppliers in the world, producing more than 1 billion sterile units per year. We have a very rigorous quality management system that applies not only to Pfizer sites but also to all our suppliers globally.

Our COVID-19 vaccine is made using the same quality standard and the same rigor as all the other Pfizer products. Given the urgent public health need to develop a vaccine in a responsible way that meets safety requirements, we collaborated closely with regulatory and health authorities around the world – compressing stages that have taken years into months, and those that have taken months into weeks by doing steps in parallel rather than sequentially while maintaining high scientific standards. The pharmaceutical industry is one of the most stringently regulated industries in the world and rightly so as patient safety is key. Our COVID-19 vaccine underwent rigorous regulatory agency review prior to administration to patients. Any changes to the product particulars such as the addition of new manufacturing sites continues to require review and approval by regulators.

We have full confidence in our careful approach to vaccine development and in the overall safety profile of our vaccine. The independent data monitoring committee continues to monitor safety data

generated by our study. The data demonstrates the vaccine is generally well tolerated across all populations and we have received regulatory approvals or authorizations down to age 5 as we continue to study evaluate the vaccine in younger age groups.

We believe public education in collaboration with patient organizations, medical and public health institutions is critical to increasing awareness of the importance of vaccinations and build trust across all levels of society. It's important to explain not only as Pfizer, but collectively with industry partners, patient organizations and government and public health institutions, how vaccine developers are coordinating closely with the U.S. FDA and other leading regulators such as EMA, to conduct key activities in parallel, to allow us to significantly accelerate vaccine development without skipping any steps or sacrificing safety and efficacy assessments.

***

To conclude, we recognize and are concerned by the complex evolution of the pandemic and how it continues to have severe impacts on individuals, families and communities. We continue to regularly evaluate the risks COVID-19 poses to people, particularly in the most vulnerable geographies, and among the most vulnerable groups of society, and adapt our response. We hope the details provided above give a sense of the many angles we are covering in our efforts to ensure equitable access and to fulfill our human rights responsibilities.

At the same time, we recognize that deep-seated challenges to achieve the right to health cannot be solved working alone, particularly during an unprecedented pandemic. For this reason we continue to invest our time and resources working in partnership with governments, international organizations, patient organizations and local healthcare systems so that we can, together, tackle systemic challenges.

We are committed to continue evolving and improving our response to this pandemic where we can, and we strongly welcome the opportunity to engage with others to share challenges, lessons learned and to build collaborative solutions to improve equitable healthcare access globally. As such, we would be very pleased for the opportunity to continue this dialogue and to answer additional questions you may have.

Please note that we remain fully focused on getting high-quality, safe, and effective vaccines and treatments to patients all over the world as quickly as possible and to helping end this deadly pandemic.

Sincerely,

Dr. Albert Bourla, D.V.M., Ph.D.
Chairman of the Board
Chief Executive Officer