March 9, 2022

Albert Bourla
Chairman and Chief Executive Officer Pfizer
235 E 42nd St
New York, NY 10017

Re: Access to reference Paxlovid and allowance of co-formulation and co-packaged medicines

Dear Mr. Bourla,

We are writing you as civil society representatives to the Access to COVID-19 Tools Accelerator working in the Therapeutics Pillar.

We have learned that Pfizer is not yet providing reference Paxlovid to all potential generic producers so that they can undertake the bioavailability and bioequivalence studies mandated by national regulatory authorities globally and by the WHO Prequalification Program. Such studies are a necessary precursor to the cross-over trials that some countries like India might require. The failure to supply reference product would require potential generic entrants to violate human subject rights under the Declaration of Helsinki by repeating clinical trials where the scientific knowledge concerning safety and efficacy has already been confirmed by your own clinical trials. By delaying effective treatment to many people worldwide, it can be argued that a lack of reference product will contribute to ongoing spread of COVID-19 infection and bad outcomes for patients.

We request that Pfizer supply reference supplies on a not-for-profit basis to all potential generic producers whether or not they are Medicines Patent Pool licensees. There are several mechanism that could achieve this: selling Paxlovid directly to such producers, cooperating with a commercial contract research organization, or working with a non-commercial organization authorized to distribute to potential generic entrants to conduct bioequivalence studies.

In addition, we request that Pfizer agree to provide nirmatrelvir + ritonavir to investigators conducting clinical trials and implementation studies of this product including its use in combination with other anti-covid therapies. This is really important, particularly at this point in such a large pandemic where new therapies are actively being studied, released, and approved, and understanding the impact of combination therapy is imperative for healthcare workers around the world. It is also important for researchers to investigate combination antiviral regimens, given the risk of drug resistance to single antivirals or single antivirals plus boosters. Pfizer should consider donating nirmatrelvir + ritonavir for the purpose of such studies or at least supplying it on a not-for-profit basis.

Relatedly, we request that Pfizer remove the restriction in paragraph 2.3 of its license agreement with the Medicines Patent Pool that requires prior approval by Pfizer before MPP

licensees can co-formulate or co-package nirmatrelvir + ritonavir or its components with any other "substance, products, intermediate and/or active pharmaceutical ingredient." Although it would be reasonable to condition marketing of any such co-formulated or co-packaged product on that product being included in clinical guidance and having received regulatory approval equivalent to that required elsewhere in the MPP license, Pfizer should not stand in the way of such combination or co-packaged products that might have complementary or additional methods of action and thus favorably impact clinical outcomes and/or reduce the risk of drug resistance.

Finally, it has been recently reported that Pfizer intend to set aside only 10 million courses of treatment in 2022 (out total expected production of 120 million courses) for low- and middle-income countries, including presumably both those in the MPP licensed territory and the many middle-income countries it has reserved for its own exclusive sales. This 10 million course supply will be grossly insufficient and disproportionately small to meet the needs of higher-risk patients and other patients in LMICs who would benefit from treatment with nirmatrelvir + ritonavir (estimated proportionate set aside should be 50-67%). We note as well that Pfizer has stated an intent to charge higher tiered prices in the middle-income countries it has reserved for its own exclusive sales. We request that Pfizer commit to reserve supplies proportionate to need in all LMICs and that it further commit to selling at a no-profit price in those countries until and unless generic nirmatrelvir + ritonavir becomes available.

We look forward to your immediate and favorable response to these requests.

Very truly yours,

Access to COVID-19 Accelerator, Civil Society Representatives to the Treatment Pillar
(Please reply to Brook K. Baker, b.baker@northeastern.edu)