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UK grants temporary authorisation for emergency use of Pfizer COVID-19 vaccine

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Pfizer Inc and BioNTech SE announced that the Medicines & Healthcare Products Regulatory Agency (MHRA) in the UK has granted a temporary authorisation for emergency use for their COVID-19 mRNA vaccine (BNT162b2), against COVID-19.

This constitutes the first Emergency Use Authorisation following a worldwide Phase 3 trial of a vaccine to help fight the pandemic. Pfizer and BioNTech are anticipating further regulatory decisions across the globe in the coming days and weeks and are ready to deliver vaccine doses following potential regulatory authorisations or approvals. The distribution of the vaccine in the UK will be prioritised according to the populations identified in guidance from the Joint Committee on Vaccination and Immunisation (JCVI).

Albert Bourla, Chairman and Chief Executive Officer, Pfizer said, “As we anticipate further authorisations and approvals, we are focused on moving with the same level of urgency to safely supply a high-quality vaccine around the world. With thousands of people becoming infected, every day matters in the collective race to end this devastating pandemic.”

Ugur Sahin, MD, CEO and Co-Founder, BioNTech said, “We believe that the roll-out of the vaccination programme in the UK will reduce the number of people in the high-risk population being hospitalised. Our aim is to bring a safe and effective vaccine upon approval to the people who need it.

The MHRA’s decision is based on a rolling submission, including data from the Phase 3 clinical study, which demonstrated a vaccine efficacy rate of 95 per cent ($p<0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from seven days after the second dose. Today’s decision also is based on a review of Pfizer’s and BioNTech’s Chemistry, Manufacturing and Control (CMC) data for BNT162b2.

In July 2020, Pfizer and BioNTech announced an agreement with the UK to supply 30 million doses of the BNT162b2 mRNA-based vaccine, once authorised for emergency use. That agreement was increased to 40 million doses in early October. The delivery of the 40 million doses will occur throughout 2020 and 2021, in stages, to ensure an equitable allocation of vaccines across the geographies with executed contracts.

Dr Alok Roy, Chair FICCI Health Services Committee and Chairman Medica Group of Hospitals said, “It is a much -awaited need of the time. It is the vaccine which is seen as the best chance for the world to get back to some semblance of normality amid a global pandemic which has killed nearly 1.5 million people and upended the global economy. According to the UK government the vaccine is effective by 70-80%. If this fact is true, then it will be a game changer. However, in India as the temperature is warmer than the European countries we will have to wait till we get approval from the Indian Government.”