Pfizer and BioNTech to Submit Emergency Authorization for Coronavirus Vaccine Today



The drug companies are seeking the first coronavirus vaccine regulatory OK in the United States from the FDA.

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Pfizer and BioNTech say that their vaccine, called BNT162b2, could be available by the middle to end of December. Distribution would begin with high-risk populations in the United States.

The final analysis of Phase 3 of the clinical trial found that BNT162b2 was 95% effective in preventing infections and caused no serious safety concerns. This is based on a trial pool of 43,000 volunteers.

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“Filing in the U.S. represents a critical milestone in our journey to deliver a Covid-19 vaccine to the world, and we now have a more complete picture of both the efficacy and safety profile of our vaccine, giving us confidence in its potential,” Pfizer CEO Albert Bourla said in a statement.

As explained by CNN, an Emergency use authorization (or EUA) is not the same as full approval. It allows a product to be used in advance of all evidence being available for approval. For the FDA to grant the EUA, it will determine whether the vaccine’s “known and potential benefits outweigh its known and potential risks.”

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