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COVID-19 vaccine candidate by Pfizer, BioNTech shows more than 90% effectivity

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Vaccine candidate was found to be more than 90% effective in preventing COVID-19 in participants withoutevidence of prior SARS-CoV-2 infection in the first interim efficacy analysis

Pfizer Inc. and BioNTech SE have announced their mRNA-based vaccine candidate, BNT162b2, against SARS-CoV-2 has demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection, based on the first interim efficacy analysis conducted on November 8, 2020 by an external, independent Data Monitoring Committee (DMC) from the Phase 3 clinical study.

“The first interim analysis of our global Phase 3 study provides evidence that a vaccine may effectively prevent COVID-19. This is a victory for innovation, science and a global collaborative effort,” said Prof. Ugur Sahin, BioNTech co-founder and CEO. “When we embarked on this journey 10 months ago this is what we aspired to achieve. Especially today, while we are all in the midst of a second wave and many of us in lockdown, we appreciate even more how important this milestone is on our path towards ending this pandemic and for all of us to regain a sense of normality. We will continue to collect further data as the trial continues to enroll for a final analysis planned when a total of 164 confirmed COVID-19 cases have accrued.”

The Phase 3 clinical trial of BNT162b2 began on July 27 and has enrolled 43,538 participants to date, 38,955 of whom have received a second dose of the vaccine candidate as of November 8, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds.

The trial is continuing to enroll and is expected to continue through the final analysis when a total of 164 confirmed COVID-19 cases have accrued. The study also will evaluate the potential for the vaccine candidate to provide protection against COVID-19 in those who have had prior exposure to SARS-CoV-2, as well as vaccine prevention against severe COVID-19 disease.

In addition to the primary efficacy endpoints evaluating confirmed COVID-19 cases accruing from 7 days after the second dose, the final analysis now will include, with the approval of the FDA, new secondary endpoints evaluating efficacy based on cases accruing 14 days after the second dose as well. The companies believe that the addition of these secondary endpoints will help align data across all COVID-19 vaccine studies and allow for cross-trial learnings and comparisons between these novel vaccine platforms.