Review on Coronavirus Infection Disease-2019 (COVID-19) Vaccine Efficacy and Safety

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Background: On February 4, 2020, pursuant to section 504(b)(1)(c) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there was a public health emergency that has a significant potential to affect national security. On March 27, 2020, the Secretary of HHS declared that circumstances exist to justify the authorization of emergency use of drugs and biological products during the COVID-19 pandemic pursuant to section 564 of the Act; (1) Severe Acute Respiratory Syndrome-Coronavirus-2 can cause a serious or life-threatening disease or condition, included severe respiratory illness, to human infected by the virus; (2) based on the totality of scientific evidence available to FDA, it was reasonable to believe that the two COVID-19 vaccines may be effective in preventing COVID-19 under the Emergence Use Authorization (EUA), and the known-benefit outweigh the potential-risk; (3) there is no adequate, approved, and available alternative to the EUA of the two COVID-19 vaccines.

Hypothesis: To determine the risks and benefits of these COVID-19 messenger-RNA vaccines (i.e., BNT162b2 and mRNA-1273).

Methods: BNT162b2-vaccine study included phase I/II, and phase-III randomized double-blind, placebo controlled. The efficacy-data was obtained 7-day after completion of the vaccination in (n=36,621) and Vaccine Efficacy (VE) is calculated using posterior-probability that true VE is >30%. The safety-data was obtained in (n=38,000), 16-year and older with median follow-up of 2-month. The mRNA-1273 efficacy-data (n=30,418), with one-sided $p<0.0001$ from the stratified Cox-proportional hazard-model to test the null-hypothesis of VE (=/<) 30%.

Results: BNT162b2-vaccine reported 6-death (2 in vaccine and 4 in placebo), while mRNA-1273 vaccine had 13-death (6 in vaccine and 7 in placebo).

Conclusion: Both vaccines met the success criterion and have shown to be clinically meaningful.