MODULE 2.6.1. INTRODUCTION

2.6.1. INTRODUCTION

There is an urgent need for the development of a new prophylactic vaccine given the threat posed by the increasing number of globally distributed outbreaks of Severe Acute Respiratory Syndrome (SARS)-CoV-2 infection and thus its associated disease Coronavirus Disease 2019 (COVID-19). A Lipid Nanoparticle (LNP)-formulated ribonucleic acid (RNA)-based vaccine would provide one of the most flexible, scalable, and fastest approaches to provide protection against new, fast spreading, virus infection. The development of an RNA-based vaccine encoding a viral antigen that is translated by the vaccinated organism to protein to induce a protective immune response provides significant advantages over more conventional vaccine approaches.

BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048) is a vaccine intended to prevent COVID-19, which is caused by SARS-CoV-2. BNT162b2, otherwise known as BNT162b2 (V9), is a nucleoside modified mRNA (modRNA) expressing full-length spike (S) protein with two proline mutations (P2) to lock the transmembrane protein in an antigenically optimal prefusion conformation. The vaccine is formulated in lipid nanoparticles. The LNP is composed of 4 lipids: ALC-0315, ALC-0159, DSPC, and cholesterol. Other excipients in the formulation include sucrose, NaCl, KCL, Na_2HPO_4, and KH_2PO_4. The drug product is a preservative-free, sterile dispersion of RNA formulated in LNP in aqueous cryoprotectant buffer for intramuscular (IM) administration. The RNA drug substance is the only active ingredient in the drug product. The drug product is a concentrate for injection and filled a (b) (4) mg/mL in glass vials and closed with stoppers and flip off crimping cap.

2.6.1.1. Proposed Indications

BNT162b2 is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older. The dose selected for BNT162b2 for commercial use is 30 ug RNA administered IM on Days 1 and 22.