

MODULE 2.6.1. INTRODUCTION

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2.6.1. INTRODUCTION

Given the threat posed by Severe Acute Respiratory Syndrome (SARS)-Coronavirus (CoV)-2 variants and their sub-lineages continued evolution and the precipitated waves of new infections, there is an urgent need for the development of new prophylactic variant vaccines to confer better protection against contemporaneous circulating lineages causing disease within a single season. The development of an RNA-based vaccine encoding a viral antigen that is translated in cells of vaccinated individuals to protein to induce a protective immune response provides significant advantages over more conventional vaccine approaches.

BNT162b2 LP.8.1 monovalent vaccine (BioNTech code number BNT162, Pfizer code number PF-07302048) is intended to prevent COVID-19 caused by SARS-CoV-2. BNT162b2 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 (LNPs). The LNP is composed of 4 lipids: ALC-0315, ALC-0159, DSPC, and cholesterol. Other excipients in the formulation include sucrose, tromethamine (Tris base), and Tris hydrochloride. 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.

2.6.1.1. Proposed Indications

COMIRNATY, including variant vaccines, is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).