1.3.4 FINANCIAL CERTIFICATION AND DISCLOSURE – BIAS STATEMENT

Protocol Number: C4591001

Study Title: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study To Evaluate The Safety, Tolerability, Immunogenicity, And Efficacy Of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 In Healthy Individuals

STEPS TAKEN TO MINIMIZE THE POTENTIAL FOR BIAS

The above-referenced trial was conducted according to ICH Good Clinical Practices. The study was conducted according to Pfizer SOPs.

Other processes used to minimize potential bias are as follows:

- The facilities performing the safety and efficacy evaluations were determined to be acceptable based on appropriate certification or historical performance and/or qualifications and credentials.
- Electronic diaries were used to collect patient reported outcomes, to ensure real time completion of outcomes questionnaires.
- Subjects were allocated randomly to vaccine group through use of an Interactive Response System.
- An independent external data monitoring committee (DMC), operating under a written charter, reviewed unblinded safety data on a weekly basis during Phase 2/3 and was responsible for the review of the efficacy interim analysis.
- Ongoing accrual of protocol-defined cases was monitored in a blinded manner and, when sufficient cases were available, the unblinded analysis was performed by a limited number of individuals who are not involved in ongoing conduct of the study (statistical team supporting the DMC).
- Microbiological confirmation of cases by Polymerase Chain Reaction (PCR) was performed by individuals blinded to treatment allocation in a central laboratory.
- An independent unblinded submissions team separate from the study team, operating under a written charter, analyzed defined endpoints for regulatory submissions (EUA, MAA). Analyses were stored on restricted sites. Access to the restricted sites was governed by charter and tracked.
- Investigator trial sites were monitored frequently.

- The validity of the data collected during the study was confirmed by standard monitoring procedures.
- During the course of processing, analyzing and reporting data from clinical trials, Pfizer applied procedures (e.g., querying data through electronic edit checks and clinical reviews) designed to ensure that errors were eliminated.
- Appropriate statistical methods were employed by use of an approved statistical analysis plan.
- The study report was reviewed by the Sponsor's Quality Control Group.

1.3.4 FINANCIAL CERTIFICATION AND DISCLOSURE – BIAS STATEMENT

Protocol number: BNT162-01

Study title: A multi-site, Phase I/II, 2-part, dose-escalation trial investigating the safety and immunogenicity of four prophylactic SARS-CoV-2 RNA vaccines against COVID-19 using different dosing regimens in healthy and immunocompromised adults

STEPS TAKEN TO MINIMIZE THE POTENTIAL FOR BIAS

The clinical study BNT162-01 is being conducted according to ICH Good Clinical Practices, relevant regulatory guidance, and BioNTech SOPs. The study is still ongoing clinically.

The study has an open-label exploratory design and does not include testing of a formal statistical hypothesis.

Other processes used to minimize potential bias are as follows:

- The contract research organization (CRO) conducting the study was qualified according to the sponsor's standard operating procedures (SOPs) in cooperation with the sponsor's quality assurance department.
- Study sites were monitored frequently and the validity of the data collected during the study was confirmed according to BioNTech SOPs.
- Data verification was performed on the data in the database using computerized checks looking for missing data, inconsistencies, and incorrect values. A manual review of the data was also performed. If necessary, data clarification forms were generated and transmitted to the site. The investigator was requested to confirm or make corrections or enter additional or missing data as required. Further data quality control measures were defined in the data validation plan. In addition, a reconciliation of reportable adverse events between the global drug safety and clinical databases as well as a reconciliation of other non-CRF data were performed.
- Appropriate statistical methods were employed by use of an approved statistical analysis plan according to BioNTech SOPs.
- The study report was reviewed and subjected to quality control checks according to BioNTech SOPs.