REQUEST FOR PROPRIETARY &

NON-PROPRIETARY NAME REVIEW

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1. APPLICANT CONTACT INFORMATION

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2. PROPOSED PRIMARY AND ALTERNATE PROPRIETARY NAMES

The primary proposed proprietary name for Agency consideration is COMIRNATY.

The trademark application serial number is 88942267 (filed by BioNTech SE) for COMIRNATY. The application was filed at the United States Patent and Trademark Office on June 1, 2020 by BioNTech SE. The Notice of Allowance has not yet issued.

Should this name not be found acceptable, an alternate name will be provided at that time.

3. INTENDED PRONUNCIATION

koh-MER' nah-tee

4. DERIVATION OF PROPRIETARY NAME

The proposed proprietary name COMIRNATY is an invented word with no inherent meaning.

5. INTENDED MEANING OF PROPRIETARY NAME MODIFIERS

Not applicable.

6. PROPOSED ESTABLISHED NAME

COVID-19 mRNA Vaccine (nucleoside modified)

7. PHARMACOLOGIC/ THERAPEUTIC CATEGORY

Prophylactic vaccine.

8. PROPOSED INDICATION FOR USE

Active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus, in individuals 16 years of age and older.

9. PRESCRIPTION STATUS

To be administered by a qualified healthcare professional.

10. DOSAGE FORM, PRODUCT STRENGTH(S)

Concentrate for solution for injection.

5-Dose Vial is supplied as a white to off-white sterile frozen liquid, packaged in a clear glass 2 mL vial with a rubber stopper, aluminum overseal and flip off cap.

A single vial will be used to prepare a diluted dosing solution that is used to prepare doses for multiple individuals. The concentrated solution in the vial requires dilution with sterile 0.9% Sodium Chloride Injection, USP. After dilution, the vials contain a sufficient volume to supply 5 doses, where each 0.3 mL dose contains 30 µg vaccine for intramuscular injection.

11. ROUTE OF ADMINISTRATION

For intramuscular injection only.

12. USUAL DOSAGE, FREQUENCY OF ADMINISTRATION, MAXIMUM DAILY DOSE

Administered intramuscularly as a series of two 30 µg doses of the diluted vaccine solution (0.3 mL each) according to the following schedule: A single 0.3 mL dose followed by a second 0.3 mL dose 21 days later.

13. DOSING IN SPECIFIC POPULATIONS

No specific information will be provided for modifications that are dependent on renal and/or hepatic function. There will be no gender-based modifications.

14. INSTRUCTIONS FOR USE

After thawing, each vial of vaccine must be diluted with 1.8 mL sterile 0.9% Sodium Chloride Injection, USP. After dilution, the vial contains five 30 µg doses of 0.3 mL per dose. Individual 0.3 mL doses should be withdrawn from the vial and administered intramuscularly in the deltoid muscle of the non-dominant arm.

15. STORAGE REQUIREMENT

Vaccine vials must be immediately stored between -80 ºC and -60 ºC (-112 ºF to -76 ºF), protected from light and kept in the original packaging until ready for use.

16. HOW SUPPLIED AND PACKAGING CONFIGURATION

The vaccine will be supplied frozen in -80 ºC thermal containers with dry ice, in cartons each containing 195 vials.

17. LIKELY CARE ENVIRONMENT(S) FOR DISPENSING AND USE

This vaccine will be administered by a qualified healthcare professional.

18. DELIVERY SYSTEM, MEASURING DEVICE

After dilution, each 0.3 mL dose of vaccine should be withdrawn from the vial with a commercially available disposable sterile syringe with appropriate graduations and delivered with a needle appropriate for intramuscular injection.

19. ASSESSMENTS OF PROPRIETARY NAME, PACKAGING, AND/OR LABELING

The Sponsor has evaluated the proposed primary proprietary name of COMIRNATY for this vaccine and considers the name safe, not misleading, or over-promising. However, no information of this nature is included in the current application.