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| Mfr Report # | (b) (6) |
| UF/Importer Report # | |
| FDA Use Only | |

| A. PATIENT INFORMATION | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------|
| 1. Patient Identifier US3402316 | 2. Age at Time of Event: 29 Years or Date of Birth: (b) (6) /1990 | 3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male | 4. Weight 168.2 lbs or 76.3 kgs |
| In confidence | | | |
| B. ADVERSE EVENT OR PRODUCT PROBLEM | | | |
| 1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) | | | |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) | | | |
| <input type="checkbox"/> Death: (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices) | | | |
| 3. Date of Event (mm/dd/yyyy) 10/18/2020 | | 4. Date of This Report (mm/dd/yyyy) 11/22/2020 | |
| 5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) Drug exposure before pregnancy [Drug exposure before pregnancy] | | | |
| Case Description: This 29-year-old, White, female subject (US3402316) was participating in A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (mRNA-1273-P301) and became pregnant. | | | |
| The subject's medical history, as provided by the investigator, included chromosomal abnormality 1 and 4, anxiety, depression, binge eating disorder and allergy to morphine. The pregnancy history of the subject included 2 prior continued in additional info section... | | | |
| 6. Relevant Tests/Laboratory Data, Including Dates #1 09/11/2020 Pregnancy test urine (continued) #2 10/25/2020 Pregnancy test urine (continued) | | | |
| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 Pregnancy Date of LMP (MM-DD-YYYY) 09/25/2020 #2 --/--/2000 to Ongoing Current Condition, (Continued) #3 01/14/2012 to 01/14/2012 Historical Condition, (Continued) continued in additional info section... | | | |

| C. SUSPECT PRODUCT(S) | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 1. Name (Give labeled strength & mfr/labeler) (Regimens Continued) | | | |
| #1. mRNA-1273 vs Placebo (Code not broken) | | | |
| #2. | | | |
| 2. Dose, Frequency & Route Used | | 3. Therapy Dates (if unknown, give duration) from/to (or best estimate) | |
| #1. Blinded, Information withheld. | | #1. 08/09/2020 to 08/09/2020 | |
| #2. | | #2. | |
| 4. Diagnosis for Use (Indication) | | 5. Event Abated After Use Stopped or Dose Reduced? | |
| #1. COVID-19 (Continued) | | #1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply | |
| #2. | | #2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply | |
| 6. Lot # | 7. Exp. Date | 8. Event Reappeared After Reintroduction? | |
| #1. Blinded | #1. Blinded | #1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply | |
| #2. | #2. | #2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply | |
| 9. NDC# or Unique ID | | | |
| 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 1) WELLBUTRIN (BUPROPION HYDROCHLORIDE) 12/--/2019 to ongoing continued in additional info section... | | | |
| G. ALL MANUFACTURERS | | | |
| 1. Contact Office (and Manufacturing Site for Devices) | | 2. Phone Number | |
| Name ModernaTX, Inc. David Martin MD. | | 617-335-1804 | |
| Address 200 Technology Square Cambridge, MA 02139 United States of America | | 3. Report Source (Check all that apply) | |
| Email Address | | <input type="checkbox"/> Foreign <input checked="" type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input checked="" type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other: | |
| 4. Date Received by Manufacturer (mm/dd/yyyy) 11/04/2020 | | 5. (A) NDA # IND # 019635 BLA # PMA/ 510(k) # Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes | |
| 6. If IND, Give Protocol # mRNA-1273-P301 | | | |
| 7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #2 | | | |
| 9. Manufacturer Report Number (b) (6) | | 8. Adverse Event Term(s) Drug exposure before pregnancy | |
| E. INITIAL REPORTER | | | |
| 1. Name and Address Dr Frank Eder Meridian Clinical Research, LLC Binghamton, New York UNITED STATES | | | |
| Phone # (b) (6) | | Email Address (b) (6) @mcrmed.com | |
| 2. Health Professional? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | 3. Occupation Physician | |
| | | 4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unk | |

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

ADDITIONAL INFORMATION

B5. EVENT DESCRIPTION (Continued)

pregnancies: live birth on 14 Jan 2012; live birth on 21 Jun 2015. Concomitant medications reported as taken since conception included bupropion hydrochloride and celecoxib. While participating in this study, and preceding this event, the subject experienced the non-serious event of Covid-19 (b) (6)

The subject received the first dose of blinded intramuscular mRNA-1273 or placebo for SARS-CoV-2 on 09 Aug 2020. The subject's last dose of study drug prior to awareness of pregnancy was administered on 11 Sep 2020. On 11 Sep 2020, prior to second dose of study drug, urine pregnancy test was negative.

On 25 Oct 2020, the subject had a positive home pregnancy test. The first day of the subject's last menstrual period was on 25 Sep 2020. The estimated date of conception was 18 Oct 2020 and the estimated due date was estimated as 30 Jun 2020. The subject reported that she missed reinserting her ethinylestradiol/etonogestrel ring by one day, and had unprotected coitus on that particular day.

On 08 Dec 2020, the subject has an appointment scheduled with her gynecologist.

The subject had completed study drug dosing; therefore, action taken with study drug was not applicable as a result of the pregnancy.

Follow-up received on 04 Nov 2020 included deletion of pregnancy as a serious adverse event and receipt of pregnancy form with additional details.

Case Comment/Sender's Comment:

Company Comment: This case concerns a 29 year old, White, female subject who experienced a pregnancy. The pregnancy occurred 2 months 16 days after the first dose of blinded study vaccine administration and 1 month 14 days after the last dose administration. The pregnancy causality assessment was considered not applicable. The investigator assessment of relationship of study drug to pregnancy was reported as not related.

B6. LABORATORY DATA

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|------------|----------------------------------|---------|-------------------|
| 1 | 09/11/2020 | Pregnancy test urine Negative | | |
| 2 | 10/25/2020 | Pregnancy test urine Positive | | |

B7. OTHER RELEVANT HISTORY

| # | Start/Stop Date | Condition Type / Condition | Notes |
|---|--------------------------|----------------------------------------------|---------------|
| 2 | --/--/2000 Ongoing | Current Condition Binge eating | Disorder |
| 3 | 01/14/2012 01/14/2012 | Historical Condition Live birth | and 21Jun2015 |
| 4 | 07/06/2014 Ongoing | Current Condition Cytogenetic abnormality | 1 and 4 |
| 5 | --/--/2015 Ongoing | Allergy Drug hypersensitivity | Morphine |
| 6 | 12/--/2019 Ongoing | Current Condition Anxiety | |

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7 12/--/2019 Current Condition
Ongoing Depression

C4. DIAGNOSIS FOR USE (Continued)

#1:COVID-19 immunization (COVID-19 immunisation)

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

2) CELEXA [CELECOXIB] (CELECOXIB) 12/--/2019 to ongoing

Block C - Additional Dosage Regimens

| Suspect Product | 2. Dose, frequency & route used | 3. Therapy dates (if unknown, give duration) | 6. Lot # | 7. Exp. date |
|----------------------------------------|---------------------------------|-------------------------------------------------|----------|--------------|
| #1 mRNA-1273 vs Placebo Regimen # 2 | Blinded, Information withheld. | 09/11/2020 to 09/11/2020 | Blinded | Blinded |