

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

A. PATIENT INFORMATION			
1. Patient Identifier US3462076	2. Age at Time of Event: 28 Years or Date of Birth: (b) (6)/1992	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) 09/04/2020		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) PREGNANCY ON STUDY 3 DAYS AFTER VISIT 2 DOSE 2 OF STUDY MEDICATION. [Drug exposure during pregnancy, first trimester]			
Case Description: This 28-year-old, White, female subject (US3462076) 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 perennial allergic rhinitis, eczema and occasional body pain. Prior pregnancy history included one continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 08/07/2020 Pregnancy test Negative #2 09/04/2020 Pregnancy test Negative #3 09/07/2020 Pregnancy test (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) 08/11/2020 #2 --/--/2017 to Ongoing Current Condition, (Continued) #3 12/20/2017 to 12/20/2017 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. 08/07/2020 to 08/07/2020	
#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) WOMENS MULTI ONE A DAY (ASCORBIC ACID, BETACAROTENE, BIOTIN, BORIC ACID, CALCIUM 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) 11/05/2020		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 during pregnancy, first trimester	
E. INITIAL REPORTER			
1. Name and Address Dr. Edwin Kerwin Crisor, LLC Medford, Oregon UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @cirresearch.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)

prior pregnancy with live birth in 2017 with postpartum bleeding and dilation and curettage. Concomitant medications reported as taken since conception included norethisterone, vitamins not otherwise specified, paracetamol, ondansetron and influenza vaccine.

The subject was allocated to receive intramuscular mRNA-1273 or placebo for SARS-CoV-2 vaccination. The subject received the first dose of blinded study drug on 07 Aug 2020. The subject's last dose of study drug prior to awareness of pregnancy was administered on 04 Sep 2020. On 07 Aug 2020 and 04 Sep 2020, pregnancy tests were performed and were negative.

On 07 Sep 2020, the subject had a positive urine pregnancy test at an urgent care center. The first day of the subject's last menstrual period was 11 Aug 2020. The estimated date of conception was 25 Aug 2020 and the due date was estimated as 16 May 2020. The subject had been on etonogestrel implant at study visit 0/visit 1. Per subject, etonogestrel may have been removed without site's knowledge on 16 Aug 2020 when subject switched to oral contraceptive pills. It was assessed that she became pregnant during her switch in contraceptive method.

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

Follow-up information received on 05 Nov 2020 and 07 Nov 2020 included deletion of pregnancy as a serious adverse event and receipt of pregnancy form with additional details.

Case Comment/Sender's Comment:

This case concerns a 28 year old female subject, who experienced an unexpected event of drug exposure before pregnancy. The event occurred 29 days after the first dose of study medication and 1 day after the last dose administration. The dechallenge and rechallenge were not applicable (as no action was taken with study medication) for event of drug exposure before pregnancy. The event was considered unrelated to the study medication in agreement with the Investigator's assessment.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
3	09/07/2020	Pregnancy test Positive Urgent care		

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
2	--/--/2017 Ongoing	Current Condition Eczema	
3	12/20/2017 12/20/2017	Historical Condition Postpartum haemorrhage	
4	12/20/2017 12/20/2017	Procedure Uterine dilation and curettage	
5	12/20/2017 12/20/2017	Historical Condition Live birth	
6	--/--/2019 Ongoing	Current Condition Rhinitis perennial	
7	01/--/2020 Ongoing	Current Condition Pain	Occasional

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

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

PANTOTHENATE, CALCIUM PHOSPHATE DIBASIC, CHROMIC CHLORIDE, COLECALCIFEROL, CYANOCOBALAMIN, EQUISETUM ARVENSE, FERROUS BISGLYCINATE, FOLIC ACID, MAGNESIUM CHELATE, MOLYBDENUM TRIOXIDE, NICOTINAMIDE, POTASSIUM IODIDE, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN, SELENOMETHIONINE, THIAMINE MONONITRATE, TOCOPHERYL ACETATE, VITIS VINIFERA, ZINC CHELATE) Tablet 05/--/2020 to ongoing

2) TYLENOL (PARACETAMOL) 05/--/2020 to ongoing

3) TYLENOL (PARACETAMOL) 09/04/2020 to 09/06/2020

4) TULANA (NORETHISTERONE) 08/16/2020 to 09/07/2020

5) ONDANSETRON (ONDANSETRON) 10/02/2020 to ongoing

6) INFLUENZA VACCINE (INFLUENZA VACCINE) 11/05/2020 to 11/05/2020

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.	09/04/2020 to 09/04/2020	Blinded	Blinded