

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

A. PATIENT INFORMATION			
1. Patient Identifier US3602030	2. Age at Time of Event: 41 Years or Date of Birth: (b) (6) -/1979	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ lbs or ____ 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"/> Life-threatening <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
<input checked="" type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" type="checkbox"/> Other Serious (Important Medical Events)			
3. Date of Event (mm/dd/yyyy) 09/17/2020		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) Swelling to the right side of the face [Facial swelling] TINGLING ON RIGHT SIDE OF FACE [Facial paraesthesia] ANXIETY RELATED TO THE VACCINE [Immunization anxiety related reaction] LEFT SIDED CHEST WALL WARMTH [Localised feeling of warmth] LEFT SIDED TINGLING [Hemiparaesthesia] Left sided pleuritic chest pain [Pleural pain]  Case Description: This 41-year-old, Hispanic/Latino, female subject (US3602030) was participating in A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 09/22/2020 Blood pressure measurement (continued) #2 09/22/2020 Body mass index 38.4 OTHER #3 09/22/2020 Body temperature 96.4 °F #4 10/10/2020 Cardiac stress test (continued) #5 Diagnostic procedure, Unremarkable. #6 10/13/2020 Echocardiogram (Continued) continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) #1 --/--/1995 to Ongoing Current Condition, (Continued) #2 --/--/2010 to Ongoing Current Condition, (Continued) #3 --/--/2010 to Ongoing Current Condition, (Continued) continued in additional info section...			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler)			
#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. 09/11/2020 to 09/11/2020	
#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 checked="" type="checkbox"/> No <input 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) NEXPLANON (ETONOGESTREL) 06/24/2020 to ongoing 2) ADVAIR (FLUTICASONE PROPIONATE, 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) 11/09/2020		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 #5			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Facial swelling, Facial paraesthesia, Immunization anxiety related reaction, continued in additional info section...	
E. INITIAL REPORTER			
1. Name and Address Dr. Bindu Balani Hackensack University Medical Center Hackensack, NJ UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @hackensackmeridian.org	
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

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**ADDITIONAL INFORMATION****B5. EVENT DESCRIPTION (Continued)**

SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (mRNA-1273-P301), and experienced swelling to the right side of the face, tingling on right side of face, anxiety related to the vaccine, left sided pleuritic chest pain, left sided chest wall warmth and left sided tingling.

Relevant medical history, as reported by the investigator, included non-allergic rhinitis, asthma, tooth cleaning, root canal, endometriosis status post stripping, hypertension, dry eye syndrome, acid reflux, hair thinning, hyperlipidemia, insomnia, vitamin D insufficiency, left knee osteoarthritis, and multiple sinus surgeries. Relevant concomitant medications included etonogestrel, fluticasone propionate with salmeterol xinafoate, telmisartan, ciclosporin, diprophyllyne, esomeprazole magnesium, mometasone furoate, diclofenac, vitamins nos, biotin, vitamin d nos, probiotics nos, and melatonin.

On 06 Aug 2020, the subject had her tooth cleaning.

On 28 Aug 2020, the subject had a root canal done.

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 11 Sep 2020. The subject's last dose of study drug prior to event onset was on 11 Sep 2020.

The subject had no issues related to the vaccine itself.

On 17 Sep 2020, Thursday, the subject had swelling to the right side of the face, tingling on right side of face, and anxiety related to the vaccine. On 17 Sep 2020, the subject had pain chewing on her back teeth due to root canal.

On 18 Sep 2020, the subject had increasing tingling and numbness along the jaw line (along the mandibular nerve distribution of the trigeminal nerve) and increasing swelling and fullness over the maxilla bone. The subject did not have nasal discharge. Over the weekend, the subject's pain persisted.

On 21 Sep 2020, the subject visited her dentist and the dentist did not find any issues with the tooth and felt that the subject could have shingles and some other medical issues leading to the pain.

On 22 Sep 2020, the subject's vitals included body temperature 96.4 degrees Fahrenheit, blood pressure 128/81 mmHg, pulse oximetry 100 %, heart rate 98 beats per min, respiratory rate 12 breaths per min, and body mass index 38.4. The subject had swelling in cheek and jaw area. The subject did not have redness to the face, tooth decay, pain on palpation of tooth, swelling of the jaw, facial droop, nasal congestion, or nasal redness. The subject was recommended to seek an evaluation from the ear, nose, and throat specialist (ENT).

The subject had an ENT consultation for the discomfort and swelling in her face. The ENT did not find a clear explanation for the findings but suspected an odontogenic infection and referred the subject to an oral surgeon and recommended a sinus computerized tomography scan (CT). She never underwent the CT but did see an oral surgeon who thought her pain might be caused by an issue related to a dental crown at the same site. Radiographs were unremarkable.

On 27 Sep 2020, her symptoms of facial swelling and numbness, and tooth pain resolved.

On 27 Sep 2020, she developed left-sided back pain, thoracic, and pleuritic chest pain. She was evaluated by a cardiologist who recommended an echocardiogram (ECHO) and stress test. The cardiologist confirmed that the chest pain was not cardiac related. The subject had complaints of right sided chest wall numbness and has requested to be withdrawn from next dose of study drug. Additionally, the subject has requested unblinding of treatment therapy to lessen her anxiety while she undergoes evaluation of her symptoms. No additional medications or treatment was provided. She was recommended to continue to follow up with cardiologist.

On 28 Sep 2020, the subject went to her primary care physician and had a normal electrocardiogram and normal chest x-ray.

On 06 Oct 2020, the subject experienced left sided chest wall warmth while lying down and left sided tingling.

On 10 OCT 2020, regular stress test showed no ischemia.

On 13 Oct 2020, ECHO showed normal size of left ventricle cavity, normal global wall motion, visual ejection fraction 55-60-%, doppler evidence of grade 1 (impaired), diastolic dysfunction and structurally normal trileaflet aortic valve with mild grade 1 regurgitation.

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No action was taken with the study drug in response to the events of swelling to the right side of the face, tingling on right side of face, anxiety related to the vaccine, and left sided pleuritic chest pain. Study drug dose was delayed in response to the events of left sided chest wall warmth and left sided tingling.

The event, swelling to the right side of the face was considered resolved on 27 Sep 2020. The event, anxiety related to the vaccine, was considered resolved on 07 Oct 2020. The event, tingling on right side of face, was considered resolved on 28 Sep 2020. The event, left sided pleuritic chest pain, was considered resolved on 29 Sep 2020. The events, left sided chest wall warmth and left sided tingling, were considered resolved on 16 Oct 2020.

The investigator assessed the events, swelling to the right side of the face, tingling on right side of face, and anxiety as related to the vaccine, as related to study drug and not related to study procedure. The investigator assessed the event, left sided pleuritic chest pain, as not related to study drug and not related to study procedure. The investigator assessed the events, left sided chest wall warmth and left sided tingling, as related to study drug and related to study procedure.

Follow-up received on 05 Oct 2020 and 07 Oct 2020 included confirmation from the site that pain upon chewing was due to root canal, site of numbness/tingling, and course of illness. Additionally, the site reported the event of pleuritic chest pain.

Follow-up received on 09 Oct 2020 included additional event terms, updated outcome, and event details.

Follow-up received on 28 Oct 2020 and 29 Oct 2020 included updated medical history, concomitant medications, laboratory results, and treatment details; updated end date, outcome, and action taken for the events left sided chest wall warmth and left sided tingling; updated relatedness to study drug and study procedure to not related (previously not applicable) for event of left sided pleuritic chest pain. The site clarified that the subject had not seen neurology yet. All tests related to event of left sided pleuritic chest pain were negative and had no physical lab result.

Follow-up received on 09 Nov 2020 included updated medical history.

## Case Comment/Sender's Comment:

Company Comment: This case concerns a 41-year-old, Hispanic/Latino, female subject with a recent dental history of root canal (and past medical history of non-allergic rhinitis, asthma, tooth cleaning, root canal, endometriosis status post stripping, hypertension, dry eye syndrome, acid reflux, hair thinning, hyperlipidemia, insomnia, vitamin D insufficiency, left knee osteoarthritis, and multiple sinus surgeries, who experienced the unexpected events of swelling to the right side of the face, tingling on right side of face, anxiety related to the vaccine, left sided pleuritic chest pain, left sided chest wall warmth and left sided tingling. The events swelling to the right side of the face, tingling on right side of face, and anxiety related to the vaccine occurred 7 days after study vaccine administration. The event left sided pleuritic chest pain occurred 17 days after study vaccine administration. The events left sided chest wall warmth and left sided tingling occurred 26 days after study vaccine administration. Action taken with regards to study vaccine was no change. The dechallenge was not applicable. The investigator assessed the events as related to study vaccine. The company assessed the events as unrelated to the study vaccine.

The event s might be explained by the subject's recent dental surgery and medical history of sinus surgery.

## B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	09/22/2020	Blood pressure measurement	128/81 mmHg	
4	10/10/2020	Cardiac stress test No ischemia.		
6	10/13/2020	Echocardiogram  Normal size of left ventricle cavity, normal global wall motion, visual ejection fraction 55-60-%, doppler evidence of grade 1 (impaired), diastolic dysfunction and structurally normal trileaflet aortic valve with mild grade 1 regurgitation.		
7	09/22/2020	Heart rate	98 /min	
8	09/22/2020	Oxygen saturation	100 percent	FDA-CBER-2022-1614-4434458

9 09/22/2020 Respiratory rate 12 /min

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1995 Ongoing	Current Condition Asthma	
2	--/--/2010 Ongoing	Current Condition Gastroesophageal reflux disease	
3	--/--/2010 Ongoing	Current Condition Insomnia	
4	--/--/2012 Ongoing	Current Condition Dry eye	
5	--/--/2014 Ongoing	Current Condition Hypertension	
6	--/--/2015 Ongoing	Current Condition Hyperlipidaemia	
7	08/06/2020 08/06/2020	Procedure Dental cleaning	TOOTH
8	08/11/2020 Ongoing	Current Condition Alopecia	
9	08/28/2020 08/28/2020	Procedure Endodontic procedure	
10	Ongoing	Current Condition Rhinitis	
11	Ongoing	Current Condition Endometriosis	status post stripping
12	Ongoing	Current Condition Vitamin D deficiency	INSUFFICIENCY
13	Ongoing	Current Condition Osteoarthritis	left
14		Procedure Sinus operation	MULTIPLE SINUS SURGERIES

## C4. DIAGNOSIS FOR USE (Continued)

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

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## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

SALMETEROL XINAFOATE) --/--/2004 to ongoing

3) TELMISARTAN (TELMISARTAN) --/--/2012 to ongoing

4) RESTASIS (CICLOSPORIN) , 0.5 milligram per millilitre ongoing

5) ASTELIN /00085801/ (DIPROPHYLLINE) , 0.15 percent --/--/2005 to ongoing

6) NEXIUM /01479302/ (ESOMEPRAZOLE MAGNESIUM) ongoing

7) FLONASE /00908302/ (MOMETASONE FUROATE) ongoing

8) DICLOFENAC (DICLOFENAC) ongoing

9) MULTIVITAMINUM (VITAMINS NOS) ongoing

10) BIOTIN (BIOTIN) 08/--/2020 to ongoing

11) VITAMIN D NOS (VITAMIN D NOS) ongoing

12) PROBIOTICS NOS (PROBIOTICS NOS) ongoing

13) MELATONIN (MELATONIN) ongoing

## G8. ADVERSE EVENT TERMS (Continued)

Localised feeling of warmth, Hemiparaesthesia, Pleural pain