

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

A. PATIENT INFORMATION			
1. Patient Identifier US2071083	2. Age at Time of Event: 87 Years or Date of Birth: (b) (6)/1932	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"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" 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) 09/03/2020		4. Date of This Report (mm/dd/yyyy) 12/07/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) Worsening of bradycardia, chronic [Bradycardia]			
Case Description: This 87-year-old, White, female subject (US2071083) was participating in A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (mRNA-1273-P201), and experienced worsening of bradycardia, chronic.			
The subject's medical history, as provided by the investigator, included bradycardia, postmenopausal, hypothyroidism, hypercholesterolemia, and bilateral hand osteoarthritis. Concomitant medications reported included continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/03/2020 Echocardiogram (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 --/--/1980 to Ongoing, Current Condition, Postmenopause #2 --/--/2015 to Ongoing, Current Condition, Hypercholesterolaemia #3 --/--/2015 to Ongoing, Current Condition, Osteoarthritis (Bilateral) 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. 06/26/2020 to 06/26/2020	
#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) CALCIUM + VITAMIN D [CALCIUM CARBONATE;COLECALCIFEROL] (CALCIUM CARBONATE, 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) 12/01/2020		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-P201			
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 #3			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Bradycardia	
E. INITIAL REPORTER			
1. Name and Address Dr. Darrell Herrington Benchmark Research 3605 Executive Drive San Angelo, Texas 76904 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @benchmarkresearch.net	
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)

calcium carbonate/ colecalciferol, acetylsalicylic acid, gemfibrozil, lovastatin, and levothyroxine.

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 26 Jun 2020. The subject's last dose of study drug prior to event onset was on 21 Jul 2020.

On 03 Sep 2020, the subject experienced worsening of bradycardia, chronic.

On 30 Oct 2020, the subject was admitted to the hospital for observation for planned pacemaker insertion for the diagnosis of bradycardia.

On 31 Oct 2020, the subject underwent pacemaker placement insertion. On the same day, the subject was discharged from the hospital. The subject reported feeling well since the procedure; no issues were reported.

On 03 Nov 2020, transthoracic echocardiogram revealed grade 1 diastolic dysfunction.

Study drug dosing was not applicable as the subject had already received both scheduled doses.

The event, worsening of bradycardia, chronic, was reported as resolved on 31 Oct 2020.

The investigator assessed the event, worsening of bradycardia, chronic, as not related to study drug or study procedure.

Follow-up received on 25 Nov 2020 included updated event term (previously bradycardia, CHR), severity, and action taken.

Follow-up received on 01 Dec 2020 and 03 Dec 2020 included updated severity, causality to study procedure, and concomitant medication.

Case Comment/Sender's Comment:

This case concerns an 87 year old female with medical history of bradycardia and hypothyroidism, who experienced an unexpected event of worsening of bradycardia. The event occurred 2 months 7 days after the initial dose of the study medication and 1 month 12 days after the last dose. The event was considered unrelated to the study medication in agreement with the Investigator's assessment, noting the subjects history of bradycardia as an likely alternate etiology.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/03/2020	Echocardiogram		
		Grade 1 diastolic dysfunction		

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
4	--/--/2015 Ongoing	Current Condition Bradycardia	
5	05/13/2019 Ongoing	Current Condition Hypothyroidism	

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

COLECALCIFEROL) 04/01/2001 to ongoing

2) ASPIRIN [ACETYLSALICYLIC ACID] (ASPIRIN [ACETYLSALICYLIC ACID]) 04/01/2001 to ongoing

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- 3) GEMFIBROZIL (GEMFIBROZIL) 03/07/2019 to ongoing
- 4) LOVASTATIN (LOVASTATIN) 08/15/2019 to ongoing
- 5) LEVOTHYROXINE (LEVOTHYROXINE) 05/15/2019 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.	07/21/2020 to 07/21/2020	Blinded	Blinded