

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

A. PATIENT INFORMATION			
1. Patient Identifier US3512042	2. Age at Time of Event: 78 Years or Date of Birth: (b) (6)/1942	3. Sex <input type="checkbox"/> Female <input checked="" 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 checked="" type="checkbox"/> Death: 09/01/2020 (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 type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Other Serious (Important Medical Events)			
3. Date of Event (mm/dd/yyyy) 09/01/2020		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) CARDIOPULMONARY ARREST [Cardiopulmonary arrest]			
Case Description: This 78-year-old, white male (US3512042) 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 experienced cardiopulmonary arrest.			
The subject's medical history, as provided by the investigator, included paroxysmal atrial fibrillation, high blood pressure, blood cholesterol increased, cerebrovascular accident (reported by subject as "ocular thrombus stroke"), ocular thrombosis, sleep apnea syndrome, enlarged prostate, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1947 to Ongoing Current Condition, (Continued) #2 --/--/1990 to Ongoing Current Condition, (Continued) #3 --/--/1998 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. 08/12/2020 to 08/12/2020	
#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) MIRTAZAPINE (MIRTAZAPINE) 11/--/2019 to ongoing			
2) FLOMAX /01280302/ 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) 09/18/2020		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) Cardiopulmonary arrest	
E. INITIAL REPORTER			
1. Name and Address Dr. MICHAEL KOREN Jacksonville Center for Clinical Research Jacksonville, Florida UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @encoredocs.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)

allergy to sulfa, erectile dysfunction, cataract, bilateral lens implant, deafness, right hand tremor, fracture left hip, allergy to penicillin, anxiety, depression, insomnia, acetabulum fracture, hip surgery, lumbar spinal stenosis, pelvic repair surgery, chronic cholecystitis, environmental allergies, osteoarthritis, seasonal allergies, gastroesophageal reflux disease, acid reflux, dyspepsia, gastric ulcer, and constipation. Relevant concomitant medications included mirtazapine, tamsulosin hydrochloride, acetylsalicylic acid, paracetamol, diphenhydramine hydrochloride, atorvastatin calcium, losartan potassium, hydrochlorothiazide, and hydrocodone.

The subject was allocated to receive mRNA-1273 or placebo for SARS-CoV-2 vaccination. The subject received the first dose of blinded study drug on 12 Aug 2020. The subject's last dose of study drug prior to event onset was on 12 Aug 2020.

The subject tolerated the study vaccine well with only minimal local injection site tenderness. The subject was scheduled to undergo an elective cochlear implant on 03 Sep 2020 and stopped taking his acetylsalicylic acid two to five days prior to surgery.

On 30 Aug 2020, the subject was sick. On 31 Aug 2020, the subject had three episodes of vomiting and nausea. The subject did not have a fever, weight change, swelling or any other symptoms. The subject went to bed separately from his wife.

On 01 Sep 2020, in the morning, the wife found the subject who had passed away at home. Per death certificate, cause of death was cardiopulmonary arrest due to hypertension/hyperlipidemia. An autopsy was not performed.

There was no action taken with the study medication due to the event.

The subject died on 01 Sep 2020. The cause of death was reported as cardiopulmonary arrest.

The investigator assessed the event, cardiopulmonary arrest, as not related to study drug or study procedure.

Follow-up received on 18 Sep 2020 included autopsy information and cause of death per death certificate.

Case Comment/Sender's Comment:

This case concerns a 78-year-old, male subject with medical history of cerebrovascular accident, sleep apnea syndrome, blood cholesterol increased, high blood pressure and atrial fibrillation, who experienced an unexpected event of cardiopulmonary arrest. The event occurred 21 days after the first dose of study medication administration. The event was considered unrelated to the study medication in agreement with the Investigator's assessment. The event might be explained by the subject's medical history of paroxysmal atrial fibrillation, high blood pressure, blood cholesterol increased, cerebrovascular accident and sleep apnea syndrome.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1947 Ongoing	Current Condition Seasonal allergy	
2	--/--/1990 Ongoing	Current Condition Tremor	right
3	--/--/1998 Ongoing	Current Condition Gastroesophageal reflux disease	
4	--/--/1998 Ongoing	Current Condition Gastroesophageal reflux disease	
5	--/--/1998 Ongoing	Current Condition Dyspepsia	

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

6	--/--/1998 --/--/1998	Historical Condition Gastric ulcer	
7	--/--/2000 --/--/2010	Historical Condition Cataract	
8	--/--/2000 Ongoing	Current Condition Hypersensitivity	
9	--/--/2005 Ongoing	Allergy Drug hypersensitivity	sulfa
10	--/--/2005 Ongoing	Current Condition Blood cholesterol increased	
11	--/--/2005 Ongoing	Allergy Drug hypersensitivity	
12	--/--/2005 Ongoing	Current Condition Hypertension	
13	--/--/2010 Ongoing	Current Condition Erectile dysfunction	
14	--/--/2010 --/--/2010	Procedure Intraocular lens implant	bilateral
15	--/--/2010 Ongoing	Current Condition Deafness	
16	--/--/2012 Ongoing	Current Condition Sleep apnoea syndrome	
17	--/--/2013 Ongoing	Current Condition Lumbar spinal stenosis	
18	--/--/2015 Ongoing	Current Condition Atrial fibrillation	
19	06/27/2016 06/27/2016	Historical Condition Thrombotic stroke	
20	--/--/2019 --/--/2019	Historical Condition Hip fracture	left
21	--/--/2019 Ongoing	Current Condition Anxiety	
22	--/--/2019 Ongoing	Current Condition Depression	
23	--/--/2019 Ongoing	Current Condition Insomnia	

24	--/--/2019 Ongoing	Current Condition Cholecystitis chronic	
25	--/--/2019 Ongoing	Current Condition Osteoarthritis	
26	--/--/2019 Ongoing	Current Condition Constipation	
27	08/08/2019 08/08/2019	Procedure Pelvic operation	repair surgery
28	11/--/2019 Ongoing	Current Condition Prostatomegaly	
29	11/--/2019 12/--/2019	Historical Condition Acetabulum fracture	
30	11/--/2019 12/--/2019	Procedure Hip surgery	

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

(TAMSULOSIN HYDROCHLORIDE) 11/--/2019 to ongoing

3) ENTERIC ASPIRIN (ACETYLSALICYLIC ACID) --/--/2016 to ongoing

4) TYLENOL /00020001/ (PARACETAMOL) --/--/2019 to ongoing

5) BENADRYL /00000402/ (DIPHENHYDRAMINE HYDROCHLORIDE) --/--/2000 to ongoing

6) LIPITOR (ATORVASTATIN CALCIUM) --/--/2010 to ongoing

7) COZAAR (LOSARTAN POTASSIUM) --/--/2005 to ongoing

8) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) --/--/2015 to ongoing

9) HYDROCODONE (HYDROCODONE) 12/--/2019 to ongoing