

ADDITIONAL INFORMATION

B5. EVENT DESCRIPTION (Continued)

hearing loss, hypercholesterolemia, myocardial infarction, chronic obstructive pulmonary disease, cholecystectomy for cholecystitis, gastroesophageal reflux disease/reflux, gout (location unknown), and low back pain. Concomitant medications reported included salbutamol, fish oil, guaifenesin, multivitamins not otherwise specified, influenza vaccine, omeprazole, acetylsalicylic acid, carvedilol, atorvastatin, budesonide/formoterol fumarate, fluticasone, allopurinol, and tamsulosin.

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 20 Aug 2020. The subject's last dose of study drug prior to event onset was on 18 Sep 2020.

On 01 Nov 2020, the subject experienced fatal myocardial infarction. The subject's daughter reported he died of a "massive heart attack". No treatment information was reported by the investigator.

Action taken with study drug was not applicable in response to the event.

The subject died on 01 Nov 2020.

The investigator assessed the event, myocardial infarction, as not related to study drug and not related to study procedure.

Case Comment/Sender's Comment:

Company Comment: This case concerns a 77-year-old, American Indian or Alaska Native, male subject with medical history of hypercholesterolemia, myocardial infarction, chronic obstructive pulmonary disease, who experienced an unexpected event of myocardial infarction. The event occurred 2 months 13 days after the first dose of blinded study vaccine administration and 1 month 15 days after the last dose administration. The event was considered unrelated to the study vaccine in agreement with the Investigator's assessment.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1979 --/--/1979	Procedure Hand repair operation	Reconstructive Left Hand Surgery
2	--/--/2002 Ongoing	Current Condition Gastroesophageal reflux disease	
3	--/--/2004 Ongoing	Current Condition Prostatomegaly	
4	--/--/2005 Ongoing	Current Condition Deafness bilateral	
5	--/--/2005 Ongoing	Current Condition Chronic obstructive pulmonary disease	
6	--/--/2015 --/--/2015	Historical Condition Cholecystitis	
7	--/--/2015 Ongoing	Current Condition Hypercholesterolaemia	
8	--/--/2015 --/--/2015	Historical Condition Myocardial infarction	

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

9	--/--/2015 --/--/2015	Procedure Cholecystectomy	for cholecystitis
10	--/--/2015 Ongoing	Current Condition Back pain	
11	--/--/2015 Ongoing	Current Condition Gout	(Location unknown)
12	--/--/2019 --/--/2019	Historical Condition Basal cell carcinoma	
13	--/--/2019 Ongoing	Current Condition Cataract	
14		Procedure Hand repair operation	ISLAND PETICOH TRANSPLANT LEFT HAND

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 3) MUCINEX (GUAIFENESIN) 01/--/2020 to ongoing
- 4) MULTIVITAMINS [VITAMINS NOS] (MULTIVITAMINS [VITAMINS NOS]) 02/--/2019 to ongoing
- 5) INFLUENZA VACCINE (INFLUENZA VACCINE) 10/20/2020 to 10/20/2020
- 6) OMEPRAZOLE (OMEPRAZOLE) 01/--/2010 to ongoing
- 7) ASPIRIN 81 (ACETYLSALICYLIC ACID) 06/--/2015 to ongoing
- 8) CARVEDILOL (CARVEDILOL) 06/--/2015 to ongoing
- 9) ATORVASTATIN (ATORVASTATIN) 06/--/2015 to ongoing
- 10) SYMBICORT (BUDESONIDE, FORMOTEROL FUMARATE) 06/--/2015 to ongoing
- 11) SYMBICORT (BUDESONIDE, FORMOTEROL FUMARATE) 06/--/2015 to ongoing
- 12) FLUTICASONE (FLUTICASONE) 06/--/2015 to ongoing
- 13) ALLOPURINOL (ALLOPURINOL) 07/--/2018 to ongoing
- 14) TAMSULOSIN (TAMSULOSIN) 08/--/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.	09/18/2020 to 09/18/2020	Blinded	Blinded