

MEDWATCH

3500A Facsimile

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

Page 1 of 7

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

A. PATIENT INFORMATION			
1. Patient Identifier US3602051	2. Age at Time of Event: 52 Years or Date of Birth: (b) (6)/1968	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 type="checkbox"/> Death: _____ (mm/dd/yyyy) <input type="checkbox"/> Life-threatening <input checked="" 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 type="checkbox"/> Other Serious (Important Medical Events)			
3. Date of Event (mm/dd/yyyy) 10/28/2020		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) INCREASED BLEEDING INTRA OPERATIVE TIME [Intraoperative bleeding] WORSENING OF AORTIC STENOSIS [Aortic stenosis] Case Description: Cohort: >=18 and <65 years and at risk Date of Birth: 1968 ^{(b) (6)} AE: WORSENING OF AORTIC STENOSIS Start Date: 20201028 SAE Description: PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE 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: Other #1 --/--/2008 to Ongoing Historical Condition, (Continued) #2 --/--/2010 to Ongoing Current Condition, (Continued) #3 --/--/2010 to Ongoing 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. 09/17/2020 to 09/17/2020	
#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) NICOTROL (NICOTINE) 03/--/2020 to ongoing			
2) INCRUSE (UMECLINIDIUM) (UMECLINIDIUM 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) 11/17/2020		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) Intraoperative bleeding, Aortic stenosis	
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

ADDITIONAL INFORMATION

B5. EVENT DESCRIPTION (Continued)

OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED CONSIDERED AS A SERIOUS AE. SUBJECT WAS TESTED FOR COVID-19 DURING HOSPITAL ADMISSION USING A "SARS-COV-2 (COVID-19) RT-PCR BIOCARTIS - ASYMPTOMATIC" TEST WITH COLLECTION DATE ON 27OCT2020 AND RESULTS WERE NEGATIVE -- RELEVANT PROCEDURES/DIAGNOSTIC TESTS: ECHO 10/19 @ 1623: LEFT VENTRICLE: NORMAL LEFT VENTRICULAR SYSTOLIC FUNCTION. EJECTION FRACTION ESTIMATED AT 65 - 70%. GRADE 1 (MILD) LV DIASTOLIC DYSFUNCTION. MODERATE CONCENTRIC HYPERTROPHY.~

~LEFT ATRIUM: LEFT ATRIUM IS MILDLY DILATED

AORTIC VALVE: A BICUSPID VALVE CANNOT BE EXCLUDED. THERE IS CALCIFICATION OF THE AORTIC VALVE PRESENT. SEVERE STENOSIS. TRACE REGURGITATION ON COLOR-FLOW PW DOPPLER.

AV PEAK GRADIENT: 107.0MMHG AV MEAN GRADIENT: 82.0MMHG AORTIC VALVE AREA: 0.49CM2

PULMONIC VALVE: TRACE REGURGITATION ON COLOR-FLOW PW DOPPLER.

--- EKG: 10/27/2020 - ABNORMAL, 10/29/2020 - ABNORMAL,

10/30/2020 - ABNORMAL

Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: Not Applicable

Action Taken ER Visit: 1

Action Taken Concomitant Medication: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20201029

Date of hospital discharge: 20201102

Admitted to ICU?: Yes

Number of ICU days: 2

Outcome, specify: PT WITH OPEN SURGERY AND POST OP RECOVERY ONGOING

AE: INCREASED BLEEDING INTRA OPERATIVE TIME

Start Date: 20201029

SAE Description: PT UNDERWENT AVR AND WAS NOTED TO BLEED PROFUSELY AND THE SURGEON FELT THAT THAT THERE WAS NO KNOWN CAUSE OF THE SAME AND RAISED THE POSSIBILITY OF ASSOCIATION OF THE BLEEDING RISK WITH THE USE OF A STUDY PRODUCT. SUBJECT WAS TAKING THE FOLLOWING CONMEDS ON AN ONGOING BASIS PRIOR TO AVR SURGERY: MULTIVITAMIN (CENTRAVITE WITH ANTIOXIDANTS)

VITAMIN D1,

ZINC,

NICOTROL,

INCRUSE (UMECLINIDIUM)

ATORVASTATIN,

MOTRIN(IBUPROFEN),

VITAMIN C,

FISH OIL

ALBUTEROL SULFATE. -- SUBJECT TOOK/WAS ADMINISTERED THE FOLLOWING MEDICATIONS AFTER BEING ADMITTED TO THE HOSPITAL, BETWEEN THE DAY PRIOR TO SURGERY (28OCT2020) AND THE END OF AVR SURGERY:

DIPHENHYDRAMINE (BENADRYL),

DIAZEPAM (VALIUM)

ASPIRIN,

FENTANYL (SUBLIMAZE)

,MIDAZOLAM (VERSED),

METOPROLOL TARTRATE (LOPRESSOR),

ACETAMINOPHEN (TYLENOL). RELEVANT LAB TEST RESULTS ARE AS FOLLOW: (1)PTT (12.2 - 14.4 SECONDS): 10/28/20 = 14.6, 10/29/20 = 17.9, 10/30/20 = 15.1; (2)

INR (0.80 - 1.20): 10/28/20 = 1.16, 10/29/20 = ~1.52, 10/30/20 = 1.21; (3) PTT (23.4 - 38.9 SECS): 10/28/20 = 29.9, 10/29/20 = ~ND, 10/30/20 = 33.7; (4)HGB (13.0 - 17.0 GM/DL): 10/28/20 = ND, 10/29/20 = 8.8, 10/30/20 = 8.8; (5)HCT (38.7 - 50.0 %): 10/28/20 =

ND, 10/29/20 = 24.7, 10/30/20 = 25.1; (6)PLT (135 - 430 X10(3)/MCL): 10/28/20 = ND, 10/29/20 = 127, 10/30/20 = 142

Persistent or significant disability or incapacity: Yes

Action Taken: Not Applicable

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

Action Taken None: 1
Related to procedure: Not Related
Severity: Grade 4

Study Drug iterations first and closest:
Study Drug First Start Date: 20200917
Study Drug First Start Time:
Study Drug Latest Start Date: 20201014
Study Drug Latest Start Time:

Cohort: >=18 and <65 years and at risk
Date of Birth: 1968 (b) (6)

AE: WORSENING OF AORTIC STENOSIS

Start Date: 20201028

SAE Description: PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED CONSIDERED AS A SERIOUS AE. SUBJECT WAS TESTED FOR COVID-19 DURING HOSPITAL ADMISSION USING A "SARS-COV-2 (COVID-19) RT-PCR BIOARTIS - ASYMPTOMATIC" TEST WITH COLLECTION DATE ON 27OCT2020 AND RESULTS WERE NEGATIVE -- RELEVANT PROCEDURES/DIAGNOSTIC TESTS: ECHO 10/19 @ 1623: LEFT VENTRICLE: NORMAL LEFT VENTRICULAR SYSTOLIC FUNCTION. EJECTION FRACTION ESTIMATED AT 65 - 70%. GRADE 1 (MILD) LV DIASTOLIC DYSFUNCTION. MODERATE CONCENTRIC HYPERTROPHY.~
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PULMONIC VALVE: TRACE REGURGITATION ON COLOR-FLOW PW DOPPLER.

--- EKG: 10/27/2020 - ABNORMAL, 10/29/2020 - ABNORMAL,
10/30/2020 - ABNORMAL

Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: Not Applicable

Action Taken ER Visit: 1

Action Taken Concomitant Medication: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20201029

Date of hospital discharge: 20201102

Admitted to ICU?: Yes

Number of ICU days: 2

Outcome, specify: PT WITH OPEN SURGERY AND POST OP RECOVERY ONGOING

AE: INCREASED BLEEDING INTRA OPERATIVE TIME

Start Date: 20201029

SAE Description: PT UNDERWENT AVR AND WAS NOTED TO BLEED PROFUSELY AND THE SURGEON FELT THAT THAT THERE WAS NO KNOWN CAUSE OF THE SAME AND RAISED THE POSSIBILITY OF ASSOCIATION OF THE BLEEDING RISK WITH THE USE OF A STUDY PRODUCT. SUBJECT WAS TAKING THE FOLLOWING CONMEDS ON AN ONGOING BASIS PRIOR TO AVR SURGERY: MULTIVITAMIN (CENTRAVITE WITH ANTIOXIDANTS)

VITAMIN D1,

ZINC,

NICOTROL,

INCRUSE (UMECLINIDIUM)

ATORVASTATIN,

MOTRIN(IBUPROFEN),

VITAMIN C,

FISH OIL

ALBUTEROL SULFATE. -- SUBJECT TOOK/WAS ADMINISTERED THE FOLLOWING MEDICATIONS AFTER BEING ADMITTED TO THE HOSPITAL, BETWEEN THE DAY PRIOR TO SURGERY (28OCT2020) AND THE END OF AVR SURGERY:

DIPHENHYDRAMINE (BENADRYL),

DIAZEPAM (VALIUM)

ASPIRIN,

FENTANYL (SUBLIMAZE)

,MIDAZOLAM (VERSED),

METOPROLOL TARTRATE (LOPRESSOR),

ACETAMINOPHEN (TYLENOL).

Persistent or significant disability or incapacity: Yes

Action Taken: Not Applicable

Action Taken None: 1

Related to procedure: Not Related

Severity: Grade 4

Study Drug iterations first and closest:

Study Drug First Start Date: 20200917

Study Drug First Start Time:

Study Drug Latest Start Date: 20201014

Study Drug Latest Start Time:

Case Comment/Sender's Comment:

This case concerns a 52-year-old, Hispanic or Latino, male subject with medical history of aortic stenosis (diagnosed in 2020, previously reported as non-specific murmur a few years ago), chronic obstructive pulmonary disease, hyperlipidemia, tension headaches, mild bronchitis, knee replacement, smoking, bilateral knee and neck arthritis, and recurrent syncope, who experienced the unexpected events of worsening of aortic stenosis and increased bleeding intraoperative time. The events occurred 6 weeks after the first dose of study drug administration and 2 weeks after the second dose. The event of worsening aortic stenosis was considered resolved with sequelae 3 days after the surgical intervention, and the intraoperative bleeding was considered resolved on the same day. The event worsening of aortic stenosis was considered unrelated to IP in agreement with the Investigator, and the event of increased bleeding intraoperative time was considered unrelated to IP by the company and related to IP by the Investigator. The event may be explained by the subject's intake of aspirin prior to the surgical intervention. Further information is being requested.

considered unrelated to the study medication in agreement with the investigator's assessment, and likely secondary to environmental exposure as well as to the subject's underlying clinical condition.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/2008 Ongoing	Historical Condition Hyperlipidaemia	
2	--/--/2010 Ongoing	Current Condition Tension headache	
3	--/--/2010 Ongoing	Historical Condition HEADACHES (TYPE: TENSION)	
4	--/--/2011 Ongoing	Current Condition Arthritis	(TYPE: UNKNOWN; LOCATION: KNEES BILATERALLY, NECK)
5	--/--/2011 Ongoing	Current Condition Spondylitis	(TYPE: UNKNOWN; LOCATION: KNEES BILATERALLY, NECK)

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

6	--/--/2011 Ongoing	Historical Condition ARTHRITIS (TYPE: UNKNOWN; LOCATION: KNEES BILATERALLY, NECK)	
7	--/--/2012 --/--/2012	Historical Condition Knee arthroplasty	
8	--/--/2015 Ongoing	Historical Condition Chronic obstructive pulmonary disease	
9	--/--/2015 Ongoing	Current Condition Bronchitis	Mild
10	--/--/2015 Ongoing	Historical Condition BRONCHITIS (MILD)	
11	03/--/2020 Ongoing	Current Condition Aortic stenosis	(DIAGNOSED IN 2020, PREVIOUSLY REPORTED AS NON-SPECIFIC MURMUR A FEW YEARS AGO)
12	UNK 03/--/2020	Historical Condition Ex-tobacco user	
13	 Ongoing	Current Condition Syncope	Recurrent
14	UNK 03/--/2020	Historical Condition SMOKING	
15	 Ongoing	Historical Condition AORTIC STENOSIS (DIAGNOSED IN 2020, PREVIOUSLY REPORTED AS NON-SPECIFIC MURMUR A FEW YEARS AGO)	
16	 Ongoing	Historical Condition SYNCOPE (RECURRENT)	
17	 Ongoing	Historical Condition GENITAL HERPES (LAST OUTBREAK JULY 2020)	

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

BROMIDE) --/--/2015 to ongoing

3) ATORVASTATIN (ATORVASTATIN) ongoing

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

- 4) ATORVASTATIN (ATORVASTATIN)
- 5) ATORVASTATIN (ATORVASTATIN)
- 6) ATORVASTATIN (ATORVASTATIN)
- 7) MVI (VITAMINS NOS) ongoing
- 8) MOTRIN (IBUPROFEN) ongoing
- 9) MOTRIN (IBUPROFEN) 10/14/2020 to 10/14/2020
- 10) APIXABAN (ELIQUIS) 11/02/2020 to UNK
- 11) ASPIRIN (TABLET) 10/28/2020 to 10/28/2020
- 12) ASPIRIN (ECOTRIN) 10/30/2020 to UNK
- 13) AZTREONAM (AZACTAM) / D5W 10/29/2020 to 10/31/2020
- 14) AZTREONAM (AZACTAM) 10/29/2020 to 10/29/2020
- 15) BACITRACIN (50000 UNITS, USP) 10/29/2020 to 10/29/2020
- 16) BACITRACIN (OINTMENT) 11/02/2020 to UNK
- 17) BISACODYL (DULCOLAX) SUPPOSITORY 10/30/2020 to 10/31/2020
- 18) DIPHENHYDRAMINE (BENADRYL) 10/31/2020 to UNK
- 19) DIPHENHYDRAMINE (BENADRYL) 10/28/2020 to 10/28/2020
- 20) ENOXAPARIN (LOVENOX) 10/30/2020 to 11/02/2020
- 21) ETOMIDATE (AMIDATE) 10/29/2020 to 10/29/2020
- 22) INCRUSE (UMECLINIDIUM) --/--/2015 to UNK
- 23) FAMOTIDINE (PEPCID) 10/30/2020 to 10/31/2020
- 24) FENTANYL (SUBLIMAZE) 10/29/2020 to 10/29/2020
- 25) FERRIC GLUCONATE (FERRLECIT) 125 MG / NS 0.9 % 100 ML IVPB 11/01/2020 to 11/01/2020
- 26) FERROUS SULFATE 325 (65 FE) MG TABLET 11/02/2020 to UNK
- 27) FIBRIN SEALANT HUMAN (VISTASEAL) 10/29/2020 to 10/29/2020
- 28) HEPARIN (PORCINE) INJECTION 10/29/2020 to 10/29/2020
- 29) IBUPROFEN (MOTRIN) 10/31/2020 to 11/02/2020
- 30) INSULIN REGULAR (HUMULIN R) 100 UNITS / NS 100 ML INFUSION 10/29/2020 to 10/29/2020
- 31) KETOROLAC (TORADOL) 10/31/2020 to 10/31/2020
- 32) MEPERIDINE (DEMEROL) 10/29/2020 to 10/29/2020
- 33) METOPROLOL TARTRATE (LOPRESSOR) 10/29/2020 to 10/29/2020
- 34) METOPROLOL TARTRATE (LOPRESSOR) 11/01/2020 to UNK
- 35) METOPROLOL TARTRATE (LOPRESSOR) 10/30/2020 to 11/01/2020
- 36) MIDAZOLAM (VERSED) INJECTION 10/29/2020 to 10/29/2020
- 37) MIDAZOLAM (VERSED) 10 MG/2ML 10/29/2020 to 10/29/2020
- 38) MORPHINE (MORPHINE) 10/29/2020 to 10/30/2020
- 39) ONDANSETRON (ZOFTRAN) INJECTION 10/29/2020 to 11/02/2020
- 40) ONDANSETRON (ZOFTRAN) INJECTION 10/29/2020 to 10/30/2020
- 41) OXYCODONE IMMEDIATE RELEASE (ROXICODONE) 11/02/2020 to UNK
- 42) MV1
- 43) PANTOPRAZOLE (PROTONIX) 10/31/2020 to 11/02/2020
- 44) POLYETHYLENE GLYCOL (MIRALAX) (PACKET) 10/30/2020 to 11/02/2020
- 45) TRAMADOL (ULTRAM) 10/31/2020 to 11/02/2020
- 46) VANCOMYCIN (VANCOCIN) 1 G IN D5W (5% SOLN) 250 ML 10/29/2020 to 10/30/2020
- 47) WARFARIN (COUMADIN) 10/31/2020 to 10/31/2020
- 48) WARFARIN (COUMADIN) 11/01/2020 to 11/01/2020
- 49) ALBUTEROL SULFATE (SALBUTAMOL SULFATE) --/--/2015 to UNK
- 50) MOTRIN
- 51) MOTRIN UNK to 07/--/2020
- 52) ACETAMINOPHEN (OFIRMEV) 10/29/2020 to 10/30/2020
- 53) ACETAMINOPHEN (TYLENOL) 10/29/2020 to 10/29/2020
- 54) ACETAMINOPHEN (TYLENOL) 10/31/2020 to 11/02/2020
- 55) PROCHLORPERAZINE EDISYLATE (COMPAZINE) 10/29/2020 to 10/29/2020
- 56) DIAZEPAM (VALIUM) 10/28/2020 to 10/28/2020
- 57) VITAMIN C --/--/2016 to UNK
- 58) FISH OIL (FISH OIL) --/--/2018 to UNK
- 59) MULTIVITAMIN (CENTRAVITE WITH ANTIOXIDANTS) --/--/2015 to UNK
- 60) VITAMIN D1 (VITAMIN D1) --/--/2016 to UNK
- 61) ZINC (ZINC) 06/--/2020 to UNK
- 62) ACYCLOVIR 07/--/2020 to 07/--/2020

Mir Report #	(b) (6)
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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.	10/14/2020 to 10/14/2020	Blinded	Blinded