

MEDWATCH

3500A Facsimile

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

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

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A. PATIENT INFORMATION			
1. Patient Identifier US3822043	2. Age at Time of Event: 75 Years or Date of Birth: (b) (6)/1944	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 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) 10/06/2020		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) SMALL LYMPHOCYTIC LYMPHOMA [Small cell lymphocytic lymphoma]			
Case Description: Cohort: >=65 years Date of Birth: 1944 (b) (6)			
AE: SMALL LYMPHOCYTIC LYMPHOMA Start Date: 20201006 SAE Description: THE PATIENT WAS SCHEDULED FOR ROUTINE CT OF THE CHEST TO SCREEN FOR LUNG CANCER ON 9/5/2020. THE CT SHOWED AN ENLARGED LET AXILLARY LYMPH NODE THAT WAS NEW SINCE 6/26/2018. DUE TO THE FINDINGS THE SUBJECT WAS SCHEDULED FOR AN ULTRASOUND GUIDED BIOPSY. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 10/02/2020 Biopsy lymph gland (continued) #2 09/05/2020 Computerised tomogram thorax (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 --/--/1969 to Ongoing Current Condition, (Continued) #2 --/--/1969 to Ongoing Historical Condition, (Continued) #3 02/05/2014 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. 08/07/2020 to 08/07/2020	
#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) WOMEN'S MULTI [ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM AMINO ACID CHELATE;CALCIUM			
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) 11/18/2020	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 #3			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) Small cell lymphocytic lymphoma		
E. INITIAL REPORTER			
1. Name and Address Dr Christina Kennelly Tryon Medical Partners - Javara Charlotte, NC UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @tryonmed.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)

THE BIOPSY RESULTS WERE SMALL LYMPHOCYTIC LYMPHOMA.

Other medically important event: Yes

Action Taken: Not Applicable

Action Taken None: 1

Related to procedure: Related

Severity: Grade 3/Severe

Study Drug iterations first and closest:

Study Drug First Start Date: 20200807

Study Drug First Start Time:

Study Drug Latest Start Date: 20200902

Study Drug Latest Start Time:

Case Comment/Sender's Comment:

This case concerns 75 year old female subject who experienced an unexpected event of small lymphocytic lymphoma. The event occurred 2 months after the initial dose of the study medication and 1 month 5 days after the last dose. The event was considered unrelated to the study medication, noting the short latency between study medication dosing and event onset.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10/02/2020	Biopsy lymph gland		
		Partial involvement by small lymphocytic lymphoma/chronic lymphocytic leukemia		
2	09/05/2020	Computerised tomogram thorax		
		New (since 26Jun2018) enlarged left axillary lymph nodes; stable 11mm part solid nodule in the right upper lobe, unchanged since 26 Jun 2018.		

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1969 Ongoing	Current Condition Postmenopause	
2	--/--/1969 Ongoing	Historical Condition POST MENOPAUSAL	
3	02/05/2014 Ongoing	Historical Condition Pulmonary mass	
4	--/--/2014 --/--/2014	Historical Condition PRE MELANOMA LEFT FOREARM	
5	--/--/2015 Ongoing	Historical Condition Hypertension	
6	--/--/2015 --/--/2015	Historical Condition Basal cell carcinoma	

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7	11/06/2018 Ongoing	Historical Condition Chronic obstructive pulmonary disease
8	11/06/2018 Ongoing	Historical Condition Gastroesophageal reflux disease
9	11/06/2018 Ongoing	Historical Condition Mixed anxiety and depressive disorder
10	11/06/2018 Ongoing	Historical Condition Type V hyperlipidaemia
11	11/06/2018 Ongoing	Historical Condition Osteoporosis
12	11/06/2018 Ongoing	Historical Condition Restless legs syndrome
13	11/06/2018 Ongoing	Historical Condition Diverticulum
14		Historical Condition STAGE IV NON SMALL CELL LUNG CANCER
15		Historical Condition BONE METASTASIS
16		Historical Condition STAGE IIA INVASIVE MAMMARY CARCINOMA
17		Historical Condition BIOPROSTHETIC MITRAL VALVE (PORCINE)

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

PANTOTHENATE;CHROMIUM AMINO ACID CHELATE;COPPER AMINO ACID CHELATE;CYANOCOBALAMIN;EQUISETUM
ARVENSE STEM;FERROUS FUMARATE;FOLIC ACID;LAMINARIA DIGITATA POWDER;MAGNESI (ASCORBIC ACID,
BETACAROTENE, BIOTIN, CALCIUM AMINO ACID CHELATE, CALCIUM PANTOTHENATE, CHROMIUM AMINO ACID CHELATE,
COPPER AMINO ACID CHELATE, CYANOCOBALAMIN, EQUISETUM ARVENSE STEM, FERROUS FUMARATE, FOLIC ACID,
LAMINARIA DIGITATA POWDER, MAGNESIUM OXIDE, MANGANESE AMINO ACID CHELATE, NICOTINAMIDE, OENOTHERA
BIENNIS OIL, POTASSIUM AMINO ACID CHELATE, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN, SELENIUM AMINO ACID
CHELATE, THIAMINE MONONITRATE, ZINC AMINO ACID CHELATE) --/--/2010 to ongoing

2) AMLODIPINE (AMLODIPINE) --/--/2015 to ongoing

3) CALCIUM (CALCIUM) --/--/2010 to ongoing

4) PROBIOTICS NOS (PROBIOTICS NOS) --/--/2008 to ongoing

5) TRELEGY ELLIPTA (FLUTICASONE FUROATE, UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE) --/--/2018 to ongoing

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- 6) ALBUTEROL [SALBUTAMOL] (ALBUTEROL [SALBUTAMOL]) --/--/2018 to ongoing
- 7) IPRATROPIUM BROMIDE/ALBUTEROL SULFATE (IPRATROPIUM BROMIDE, SALBUTAMOL SULFATE) --/--/2018 to ongoing
- 8) BUDESONIDE (BUDESONIDE) --/--/2018 to ongoing
- 9) SIMVASTATIN (SIMVASTATIN) --/--/2009 to ongoing
- 10) PROLIA (DENOSUMAB) --/--/2017 to ongoing
- 11) IPRATROPIUM BROMIDE (IPRATROPIUM BROMIDE) --/--/2012 to ongoing
- 12) SERTRALINE (SERTRALINE) --/--/1997 to ongoing
- 13) LORAZEPAM (LORAZEPAM) ongoing
- 14) LORAZEPAM (LORAZEPAM) --/--/2018 to UNK
- 15) OMEPRAZOLE (OMEPRAZOLE) --/--/2012 to ongoing
- 16) ASPIRIN [ACETYLSALICYLIC ACID] (ASPIRIN [ACETYLSALICYLIC ACID]) --/--/2011 to ongoing
- 17) VITAMIN D3 (COLECALCIFEROL) --/--/2010 to ongoing
- 18) WOMEN'S MULTI VITAMIN --/--/2010 to UNK
- 19) PROBIOTIC --/--/2018 to UNK
- 20) SHINGRIX (VARICELLA ZOSTER VACCINE RGE (CHO)) 02/21/2019 to 02/21/2019
- 21) ALBUTEROL --/--/2018 to UNK
- 22) IPRATROPIUM-ALBUTEROL --/--/2018 to UNK
- 23) DIPHTHERIA, TETANUS, PERTUSSIS 05/01/2012 to 05/01/2012
- 24) INFLUENZA (INFLUENZA VACCINE) 10/20/2018 to 10/20/2018
- 25) PNEUMOCOCCAL 02/09/2016 to 02/09/2016
- 26) ASPIRIN --/--/2011 to UNK

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.	09/02/2020 to 09/02/2020	Blinded	Blinded