

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

A. PATIENT INFORMATION			
1. Patient Identifier US3432295	2. Age at Time of Event: 83 Years or Date of Birth: (b) (6)/1936	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: 10/02/2020 (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 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) 09/12/2020		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) SEVERE SYSTEMIC INFLAMMATORY SYNDROME IN THE SETTING OF CLL [Systemic inflammatory response syndrome] DIFFUSE BULLOUS RASH (NON-URTICARIAL) [Bullous rash] Case Description: This 83-year-old, White, male subject (US3432295) 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 diffuse bullous rash (non-urticarial), and severe systemic inflammatory syndrome in the setting of chronic lymphocytic leukemia (CLL). continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 09/30/2020 Alanine aminotransferase (continued) #2 09/20/2020 Anion gap 9 OTHER #3 09/24/2020 Anion gap 9 OTHER #4 09/30/2020 Aspartate aminotransferase (continued) #5 09/17/2020 Biopsy (Continued) #6 09/24/2020 Blood albumin 3 OTHER continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1990 to Ongoing Current Condition, (Continued) #2 --/--/2000 to Ongoing Current Condition, (Continued) #3 --/--/2005 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. 08/26/2020 to 08/26/2020	
#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 checked="" type="checkbox"/> No <input 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) LEVOTHYROXINE (LEVOTHYROXINE) --/--/2005 to ongoing 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) 10/29/2020		5. (A)NDA # IND # 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 #5			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Systemic inflammatory response syndrome, Bullous rash	
E. INITIAL REPORTER			
1. Name and Address Dr. Lindsey Baden Brigham and Womens Hospital Boston, Massachusetts UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @bwh.harvard.edu	
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 subject's current medical history, as provided by the investigator, included CLL diagnosed in Dec 2019 (no therapy, monitored), hypothyroidism, obstructive sleep apnea, open angle glaucoma, aortic root dilation, benign prostatic hyperplasia, idiopathic rhinitis, bradycardia, cataract x2, night sweats, right axillary lymphadenopathy, soft tissue thickening in left tonsillar fossa, Fuchs dystrophy, renal cyst, and stage III chronic kidney disease. Additional medical history, as provided by discharge summary, included allergy to iodine (hives). The subject's past medical history, as provided by autopsy report, included atypical CLL with clinical features of lymphomatous transformation and former smoker. Concomitant medications reported included levothyroxine, prednisolone acetate, tamsulosin, and fluticasone.

The month prior to study drug administration, the subject began to experience new symptoms consistent with CLL progression, including night sweats and fatigue. A positron emission tomography with computerized tomography (PET-CT) scan was performed on 04 Aug 2020 to further evaluate these symptoms and their potential relationship to disease transformation. Primary findings included uptake/avidity at the left base of the tongue, the posterior right greater trochanter, the right humeral head, the right femoral head, the left femoroacetabular joint space, and the right axillary lymph nodes, which were noted by the radiologist as atypical for squamous cell carcinoma metastasis and more compatible with lymphoma. Splenomegaly (16 cm along the craniocaudal axis) was also observed.

The subject received his first, and only, dose of intramuscular mRNA-1273 or placebo for SARS-CoV-2 vaccination on 26 Aug 2020, 18 days prior to initial onset of adverse event symptoms.

On 04 Sep 2020, an ultrasound guided lymph node biopsy of the right axilla was performed. Histopathology was consistent with B-cell lymphoproliferative disorder.

On 12 Sep 2020, the subject developed a raised, red papular rash on his ankles that spread up his legs and body over the following days.

On 15 Sep 2020, he had a virtual visit with his primary care physician (PCP) and then a dermatologist. The blistering rash had spread to involve more of his body. Treatment included topical triamcinolone acetate cream and clobetasol cream.

On 17 Sep 2020, the subject presented to the emergency department (ED) due to progression of the rash, which had become painful and itchy; forming large, weeping blisters. He denied mucosal lesions, fevers, chills, nausea, vomiting, abdominal pain, and diarrhea. He also denied recently starting any new medications. Initial vital signs in the ED were temperature 96.4, heart rate 88, blood pressure 128/57, respiratory rate 20, and oxygen saturation 98% on room air. Physical examination was notable for diffuse papular/vesicular/bullae rash with open blisters and yellowish serous drainage, much more confluent over groin and torso, extending into the axillae bilaterally. The rash was more vesicular over the bilateral lower extremities with confluence towards the ankles and there were several areas of skin tearing on the subject's back and in the inguinal folds. There were no lesions seen on examination of the oral mucosa, genitals, and palms. Initial laboratory results included white blood count (WBC) 25.7, neutrophils 46%, lymphocytes 42%, monocytes 9%, eosinophils 2%, and atypical cells 1%, absolute neutrophil count 11.82, absolute lymphocyte count 11.05, absolute monocyte count 2.31, platelet count (Plt) 176, blood urea nitrogen (BUN) 53, creatine 2.2 (baseline 1.1), potassium 6.1 then 5.4 on repeat, and COVID-19 polymerase chain reaction (PCR) test was negative. An electrocardiogram showed sinus rate 74, right bundle branch block with left anterior fascicular block, T-wave flattening in lateral leads without ST depressions or elevations. Dermatology was consulted and assessed the subject's presentation as consistent with bullous vasculitis, neutrophilic dermatosis, or autoimmune bullous disease. A skin biopsy showed mixed spongiotic, interface, and focally acantholytic dermatitis with mid to upper dermal perivascular and interstitial lympho-eosinophilic infiltrate and upper dermal edema. There was no intraepidermal or basement membrane deposition of IgG, IgG4, IgA, IgM, C3 or fibrinogen seen. Periodic-acid Schiff stain was negative for fungi and showed areas of vacuolar degeneration of the basement membrane zone. Immunostain for varicella zoster antigen was negative. The Pathologist suggested diagnostic considerations of atypical/extensive Grover's disease secondary to a paraneoplastic process or a Grover's disease-like hypersensitivity reaction. Treatment included topical clobetasol propionate 0.05%.

On 18 Sep 2020, blood cultures were collected and showed no growth on the final report. Relevant laboratory results included alanine aminotransferase (ALT) 14, aspartate aminotransferase (AST) 22, alkaline phosphatase (ALP) 97, total bilirubin 0.8, and lactate dehydrogenase (LDH) 381. The subject had no new symptoms and was improving.

On 22 Sep 2020, magnetic resonance imaging of the neck was performed at the request of the Ear, Nose, and Throat (ENT) specialist consulted to evaluate for potential biopsy of the lesion at the base of the subject's tongue noted on the 04 Aug 2020 PET scan. There was no mass or abnormal enhancement in the region of the left tongue to correlate with the PET scan finding. There was conglomerate right axillary and supraclavicular lymphadenopathy with possible contact with the brachial plexus. An ultrasound of

the neck was also performed for biopsy planning and showed asymmetric, edematous soft tissue thickening in the left tonsillar fossa, likely correlating to the previously seen area of avidity on prior PET-CT scan, with no well-defined mass identified. Ultimately, a biopsy was not collected from the base of the tongue/left tonsillar fossa upon ENT's evaluation.

On 23 Sep 2020, right upper extremity venous ultrasound was performed to investigate swelling and showed no evidence of deep vein thrombosis.

On 24 Sep 2020, rash was improved overall upon examination. Laboratory results included WBC 27.7, red blood cell (RBC) 3.26, hemoglobin (Hgb) 10.0, hematocrit (Hct) 31.4, BUN 35, Plt 155, and uric acid 7.6. He was discharged on oral allopurinol.

The subject had been doing well and his rash had continued to improve since being discharged until, on 29 Sep 2020, he noted that his rash had progressed to a confluent erythematous rash on his right chest, extending into the axilla.

On 30 Sep 2020, the subject presented to the ED and was later admitted to the hospital with high-grade fevers, up to 104 at home and maximum temperature of 102.2 in ED, diarrhea, and shortness of breath. His initial vital signs were temperature 101.1, heart rate 100, blood pressure 137/66, respiratory rate 18, and oxygen saturation of 94% on room air. Significant laboratory results included D-dimer 6750 ng/mL, fibrinogen 324 mg/dL, WBC 37.4, Hgb 11.2, lactate 1.9, Plt 130 K/uL, prothrombin time (PT) 18.1, international normalized ratio (INR) 1.7, BUN 30, sodium 133, uric acid 5.9, troponin 0.34, ALT 41, AST 48, ALP 227, albumin 3.2, calcium 8.2, hepatitis A antibodies positive (negative IgM, denoted no active infection), and creatinine 1.7. COVID-19 polymerase chain reaction test with nasal swab was negative. A chest, abdomen and pelvis CT showed considerable adenopathy in the chest and abdomen located in the bilateral axillae, retroperitoneum, pelvis and inguinal regions (increased since the prior PET/CT scan on 04 Aug 2020), new moderate left pleural effusion, and stable lung nodules. There was further increase in splenomegaly, now measuring 21.7 cm, with multiple low-density lesions present. Incidentally, a cystic lesion in the pancreatic neck, measuring 1.2 x 0.7 cm, was noted. Treatment included oral ceftriaxone/azithromycin and oral paracetamol. Pre admission medications were levothyroxine, prednisolone, tamsulosin, fluticasone propionate, allopurinol, triamcinolone acetonide 0.1%, and hydroxyzine.

On 01 Oct 2020, the subject's lungs were clear to auscultation bilaterally with an increased respiratory rate and increased work of breathing. He had a diffuse, resolving, macular rash involving his entire body with small patches of desquamation throughout, scattered, small, fluid-filled bullae on the dorsum of the right foot, and a large area of confluent erythema over his right chest, extending into the axilla. The subject's condition deteriorated throughout the day with the development of acute respiratory failure, requiring intubation and mechanical ventilation. He was transferred to the intensive care unit. His condition continued to worsen with pneumothorax and purpura fulminans which covered almost all of his body. PCR test results were negative for COVID-19, adenovirus, coronavirus (non-CoVID-19), human metapneumovirus, human rhinovirus/enterovirus, all influenza, all parainfluenza, respiratory syncytial virus A and B, Chlamydia pneumoniae, and Mycoplasma pneumoniae.

On the morning of 02 Oct 2020, the subject experienced cardiac arrest with pulseless electrical activity and was resuscitated. A Hematologist consulted confirmed the subject's diagnosis of purpura fulminans based on their examination and review of laboratory results. Due to the severity of his condition and poor prognosis, the subject's family elected to pursue comfort focused care. He died that afternoon, at 16:45. During this admission, the subject's labs were significant for increase in D-dimer from 6750 ng/mL to 21600 ng/mL, decrease in fibrinogen from 324 mg/dL to 151 mg/dL, decrease in platelet count from 130 K/uL to 68 K/uL, and a progressive coagulopathy with increase in INR from 2.2 to 4.2, PT from 18.1 to 46.1, schistocytes on smear, and eventually purpura fulminans/disseminated intravascular coagulation. The subject had elevated markers of inflammation, Ferritin of 1729 ng/mL and lactate dehydrogenase of 537 IU/L. The subject had a component of heart failure detected on chest x-ray and pro-brain natriuretic peptide (pro-BNP) of 18965 pg/mL. Electrocardiogram and creatine kinase - MB did not indicate myocardial infarction.

Study drug dose was delayed in response to the events.

The outcome of the events, diffuse bullous rash (non-urticarial), and severe systemic inflammatory syndrome in the setting of CLL, was fatal. The subject died on 02 Oct 2020. The cause of death, per autopsy report from 29 Oct 2020, was severe systemic inflammatory syndrome in the setting of CLL. An infiltrate composed of T-cells (CD4+ predominant) and eosinophils was present in all major organs causing a myocarditis in the heart, vacuolar interface dermatitis in the skin, necrosis and histiocytic aggregates in the bone marrow and lymph nodes, and portal based inflammation in the liver with biliary injury and endotheliitis of the portal and central veins. Infiltrates were also prominent in the bowel wall without mucosal involvement. The spleen was massively enlarged with prominent sinusoidal histiocytes present on histology. The liver and kidney also showed acute ischemic injury. Microthrombi were seen in the skin but were likely secondary to the inflammation rather than a primary vasculitis. The subject's CLL was present in the nodes and marrow but were displaced by the inflammatory infiltrate. Sections of multiple nodes and marrow did not show large cell transformation. The lungs were heavy with edema and focal acute and organizing pneumonia, but no source of sepsis was identified, and postmortem blood and lung cultures did not show significant growth. The conclusion of the autopsy report was that there was a massive immune response that was difficult to classify. There was no evidence of high-grade transformation or

progression of the CLL or a source of infection that could account for the histologic picture. The trigger for this reaction was unclear, and a relationship to subject's recent vaccination could not be excluded based on the findings.

The investigator assessed the events, diffuse bullous rash (non-urticarial), and severe systemic inflammatory syndrome in the setting of CLL, as not related to study drug or study procedure.

Follow-up received on 01 Oct 2020 and 02 Oct 2020 included updated event term to diffuse bullous rash (previously blisters), and additional event term of recurrent rash, fever, diarrhea, cardiac arrest, additional medical history, event details, labs/diagnostic test results, treatment, discharge date, and event outcome.

Follow-up received on 14 Oct 2020 included updated medical history.

Follow-up received on 21 Oct 2020 and 23 Oct 2020 included updated medical history; autopsy report which provided autopsy and event details, laboratory and diagnostic results, and cause of death.

Follow-up received on 29 Oct 2020, 30 Oct 2020, and 31 Oct 2020 included result of COVID-19 test from 01 Oct 2020, autopsy report, and medical records provided. Additionally, event terms updated to severe systemic inflammatory syndrome in the setting of CLL (previously: recurrent rash, fever, diarrhea, cardiac arrest), and diffuse bullous rash (non-urticarial) (previously: diffuse bullous rash).

Analysis of Similar Events: On 02-Nov-2020, the safety database was searched for events similar to Systemic inflammatory response syndrome, Chronic lymphocytic leukaemia, and Dermatitis bullous using the following search criteria: PT: Dermatitis bullous, Eosinophilic cellulitis, Systemic inflammatory response syndrome, Chronic lymphocytic leukaemia, Chronic lymphocytic leukaemia transformation, SMQ: Drug reaction with eosinophilia and systemic symptoms syndrome, Hypersensitivity, Immune mediated/autoimmune disorders, Severe cutaneous adverse reactions, Tumour lysis syndrome, Haematological malignant tumours.

As of 02-Nov-2020 under IND 019745 for mRNA-1273, 29 similar events were retrieved, including the current index case. One of these cases reporting the following events were previously submitted as IND Safety Reports: Swelling face (1) MCN#

(b) (6). There were 25 cases that were non-IND Safety Reports (expected and related or unexpected and unrelated or expected and unrelated to the IMP) reporting the following events: Pneumonia (10) MCN# (b) (6), (b) (6), (b) (6), (b) (6), (b) (6), (b) (6), (b) (6), (b) (6), (b) (6), (b) (6), Swelling face (1) MCN# (b) (6), Acute respiratory failure (3) MCN# (b) (6), Respiratory failure (1) MCN# (b) (6), Pyrexia (1) MCN# (b) (6), Acute kidney injury (1) MCN# (b) (6), Pancreatitis acute (1) MCN# (b) (6), Chronic lymphocytic leukaemia (1) MCN# (b) (6), Pleural effusion (1) MCN# (b) (6), B-cell small lymphocytic lymphoma (1) MCN# (b) (6), Angioedema (1) MCN# (b) (6), Metabolic acidosis (1) MCN# (b) (6), Laryngeal oedema (1) MCN# (b) (6), Renal impairment (1) MCN# (b) (6).

The above search did not yield any cases with PT systemic inflammatory response syndrome or bullous dermatitis.

Two cases of 'swelling face' were retrieved, one deemed related to IP and reported as IND report. This event happened 2 days after the second dose of IP, the subject had received dermal fillers and hyaluronic acid injections in the face 17 days prior to the event, which could have confounded the event. The other event of 'swelling face' happened 6 days after first dose of IP, was accompanied by paresthesias in the face and was deemed unrelated to IP with possible association to recent dental and sinus surgeries.

The search also yielded a case of 'Chronic lymphocytic leukaemia' and one case of 'B-cell small lymphocytic lymphoma', both deemed unrelated to IP given the short latency period between IP dose and event diagnosis (about a month for each event).

One event of 'angioedema' and another of 'laryngeal edema' were reported in 2 subjects, both events deemed unrelated to IP and most likely secondary to the subjects' concomitant medication lisinopril.

In the index case, an 83-year-old male subject experienced the unexpected fatal events of diffuse bullous rash (non-urticarial), and severe systemic inflammatory syndrome in the setting of chronic lymphocytic leukemia (CLL). The dermatologic event began as lower extremities blisters 18 days after the first dose of blinded study vaccine administration and progressed to a diffuse bullous rash despite therapeutic intervention. Symptoms of fever, diarrhea, and cardiac arrest also occurred one month and 6 days following blinded study vaccine administration. The conclusion of the autopsy report was that a massive immune response, that was difficult to classify, resulted in systemic inflammatory response syndrome in the setting of CLL. There was no evidence of high-grade transformation or progression of the CLL or source of infection to account for histologic picture. There was no clear trigger for the immune response.

Case Comment/Sender's Comment:

This case concerns an 83-year-old, male subject who experienced unexpected fatal events of diffuse bullous rash (non-urticarial), and severe systemic inflammatory syndrome in the setting of chronic lymphocytic leukemia (CLL). The dermatologic event began as lower extremities blisters 18 days after the first dose of blinded study vaccine administration and progressed to a diffuse bullous rash despite therapeutic intervention. The subject further experienced fever, diarrhea, and cardiac arrest which occurred 1 month and 6 days following blinded study vaccine administration.

The conclusion of the autopsy report is that a massive immune response that is difficult to classify resulted in systemic inflammatory response syndrome in the setting of CLL. There was no evidence of high-grade transformation or progression of the CLL or source of infection to account for histologic picture. There was no clear trigger for the immune response. As described in FDA guidance for expedited IND safety reporting, the reasonable possibility standard for evidence to suggest a causal relationship includes an occurrence of an event not commonly associated with drug (vaccine) exposure but otherwise uncommon in the population exposed. The new information from the autopsy report describes an event that is distinct from more common high-grade transformation or progression of CLL. This provides some evidence which suggests that a relationship to vaccination cannot be excluded.

While the autopsy report provides new information that is consistent with evidence suggesting a potential causal relationship articulated in guidance, assessment of causality is confounded by other evidence that the subject's CLL was evolving based on imaging obtained prior to vaccine exposure. In addition, CLL can rarely transform into histiocytic/dendritic cell sarcoma which might potentially present with a similar clinical picture. This and other potential alternative etiologies that might explain the clinical course will be the subject of any additional evaluation.

After review of the clinical details and investigator comments pertaining to this adverse event, and based upon experience to date, the Sponsor does not believe that changes to the conduct of this clinical trial are warranted. The Company will continue to monitor these and other serious adverse events reported in association with the administration of blinded mRNA-1273 SARS-CoV-2 Vaccine/vaccine placebo and will communicate any relevant changes to the protocol, Informed Consent Form, Investigator's Brochure, and/or Core Safety Information.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	09/30/2020	Alanine aminotransferase	41 OTHER	
4	09/30/2020	Aspartate aminotransferase	48 OTHER	
5	09/17/2020	Biopsy		
		B-cell lymphoproliferative disorder.		
7	09/30/2020	Blood albumin	3.2 OTHER	
8	09/30/2020	Blood alkaline phosphatase	227 OTHER	
9	09/24/2020	Blood bicarbonate	21 OTHER	
10	09/24/2020	Blood calcium	8.2 OTHER	
11	09/30/2020	Blood calcium	8.2 OTHER	
12	09/24/2020	Blood chloride	109 OTHER	
13	09/17/2020	Blood creatinine	2.2 OTHER	
14	09/20/2020	Blood creatinine	1.4 OTHER	
15	09/30/2020	Blood creatinine	1.7 OTHER	

Elevated from his baseline of 1.1, denoted acute kidney injury.

FDA-CBER-2022-1614-4434450

16	09/18/2020	Blood culture no growth.	OTHER
17	09/30/2020	Blood fibrinogen decreased to 151 mg/dL	324 mg/dl
18	09/20/2020	Blood glucose	112 OTHER
19	09/24/2020	Blood glucose	125 OTHER
20	09/30/2020	Blood glucose	110 OTHER
21	09/18/2020	Blood lactate dehydrogenase	381 international unit per litre
22	09/30/2020	Blood lactate dehydrogenase	537 international unit per litre
23	09/17/2020	Blood potassium	5.4 OTHER
24	09/30/2020	Blood sodium	133 OTHER
25	09/17/2020	Blood urea	53 OTHER
26	09/20/2020	Blood urea	36 OTHER
27	09/24/2020	Blood urea	35 OTHER
28	09/30/2020	Blood urea	30 OTHER
29	09/24/2020	Blood uric acid	7.6 OTHER
30	09/30/2020	Body temperature Maximum.	101.1 OTHER
31	09/30/2020	Computerised tomogram considerable adenopathy in the chest and abdomen located in bilateral axilla, retroperitoneum, pelvis and inguinal regions. These have increased since the prior PET/CT scan on 04 Aug 2020. New moderate left pleural effusion and stable lung nodules were noted. There was further increase in splenomegaly now measuring 21.7 cm. There were multiple low-density lesions within the spleen. Incidentally, cystic lesion in the pancreatic neck 1.2 x 0.7 cm was noted.	OTHER
32	09/17/2020	Electrocardiogram sinus rate 74, right bundle branch block with left anterior fascicular block, T-wave flattening in lateral leads without ST depressions or elevations.	
33	09/30/2020	Fibrin D dimer increased to 21600 ng/mL	6750 ng/mL
34	09/20/2020	Haematocrit	38.1 OTHER
35	09/24/2020	Haematocrit	31.4 OTHER

36	09/30/2020	Haematocrit	34.6 OTHER
37	09/20/2020	Haemoglobin	11.9 OTHER
38	09/24/2020	Haemoglobin	10.0 OTHER
39	09/30/2020	Haemoglobin	11.2 OTHER
40	09/30/2020	Hepatitis A antibody Positive Negative IgM, denoted no active infection.	
41	09/30/2020	Hepatitis A virus test Positive	OTHER
42	09/30/2020	Imaging procedure Revealed multiple bilateral pleural nodules and bibasilar atelectasis and splenomegaly.	
43	09/30/2020	International normalised ratio increased to 2.2 to 4.2	1.7 OTHER
44	09/17/2020	Lymphocyte count	11.05 OTHER
45	09/17/2020	Lymphocyte morphology abnormal	1 percent
46	09/22/2020	Magnetic resonance imaging Showed 3 cm adenopathy extending to right axilla, conglomerate right axillary and supraclavicular lymphadenopathy.	
47	09/20/2020	Mean cell haemoglobin concentration	31.2 OTHER
48	09/17/2020	Monocyte count	2.31 OTHER
49	09/17/2020	Neutrophil count	11.82 OTHER
50	09/17/2020	Physical examination diffuse paupular/vesicular/bullae rash with open blisters and yellowish serous drainage, much more confluent over groin and torso extending into axilla bilateral. Bilateral lower extremity more vesicular with confluence towards the ankles. Several areas of skin tearing on back and in inguinal folds. No lesions on palms. No oral mucosa or genital involvement. Appeared dehydrated.	
51	09/24/2020	Physical examination Rash was improved overall upon examination.	
52	09/17/2020	Platelet count	176 thousand per microlitre
53	09/20/2020	Platelet count	136 thousand per microlitre
54	09/24/2020	Platelet count	155 thousand per microlitre
55	09/30/2020	Platelet count	130 thousand per microlitre

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

decreased to 68 K/uL

56	10/02/2020	Platelet count	68 thousand per microlitre
57		Positron emission tomogram	
		areas in the left tongue, right greater trochanter and several other bony areas, as well as a right axillary lymph node, all concerning for lymphoma.	
58	09/30/2020	Prohormone brain natriuretic peptide	18965 pg/ml
59	09/30/2020	Prothrombin time	18.1 OTHER
60	09/20/2020	Red blood cell count	3.93 OTHER
61	09/24/2020	Red blood cell count	3.26 OTHER
62	09/30/2020	Red blood cell count	3.64 OTHER
63	09/17/2020	SARS-CoV-2 test Negative	
64	10/01/2020	SARS-CoV-2 test Negative Nasopharyngeal swab	
65	09/30/2020	Serum ferritin	1729 ng/mL
66	09/30/2020	Troponin T	0.34
67	09/22/2020	Ultrasound scan	
		asymmetric, edematous soft tissue thickening in the left tonsillar fossa, likely correlating to the previously seen area of avidity on prior positron emission tomography/computerized tomography (PET/CT) scan. No well-defined mass was identified.	
68	09/23/2020	Ultrasound scan	
		right upper extremity venous ultrasound showed no evidence of deep vein thrombosis in the right upper extremity.	
69	09/17/2020	White blood cell count	25.7 OTHER
70	09/20/2020	White blood cell count	23.5 OTHER
71	09/24/2020	White blood cell count	27.7 OTHER
72	09/30/2020	White blood cell count	37.4 OTHER

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
---	-----------------	----------------------------	-------

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

1	--/--/1990 Ongoing	Current Condition Rhinitis	Idiopathic
2	--/--/2000 Ongoing	Current Condition Bradycardia	
3	--/--/2005 Ongoing	Current Condition Hypothyroidism	
4	--/--/2017 Ongoing	Current Condition Benign prostatic hyperplasia	
5	--/--/2018 Ongoing	Current Condition Cataract	
6	--/--/2019 Ongoing	Current Condition Chronic lymphocytic leukaemia	No therapy, monitored
7	Ongoing	Current Condition Open angle glaucoma	
8	Ongoing	Current Condition Renal cyst	
9	Ongoing	Current Condition Aortic dilatation	
10	Ongoing	Current Condition Fuchs' syndrome	
11	Ongoing	Current Condition Sleep apnoea syndrome	
12	Ongoing	Historical Drug IODINE; Drug Reaction: Rash	
13	Ongoing	Current Condition Chronic kidney disease	
14	UNK 09/02/2020	Current Condition Cataract	
15		Historical Condition Chronic lymphocytic leukaemia	Atypical with clinical features of lymphomatous transformation
16		Historical Condition Ex-tobacco user	
17	Ongoing	Current Condition Night sweats	

18	Ongoing	Current Condition Lymphadenopathy
----	---------	--------------------------------------

19	Ongoing	Current Condition Soft tissue swelling
----	---------	---

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

2) TAMSULOSIN (TAMSULOSIN) --/--/2017 to ongoing

3) FLUTICASONE (FLUTICASONE) --/--/2000 to ongoing

4) PREDNISOLONE ACETATE (PREDNISOLONE ACETATE) , 1 percent UNK to 10/02/2020