

Participant ID	MCN
US3212326	(b) (6)
Preferred Term:	Autonomic Dysfunction
Treatment Assignment:	mRNA-1273
Relationship	Related
Baseline SARS-CoV-2	Negative

A 46 year-old female participant with medical history of hypothyroidism, left thyroidectomy, benign left thyroid nodule and bilateral tubal ligation experienced a serious event of autonomic dysfunction. The participant received the first dose of blinded study drug on 27 Aug 2020. The participant's last dose of study drug prior to event onset was on 25 Sep 2020.

On 18 Oct 2020, the participant reported symptoms of intermittent palpitations and intermittent dizziness. She was unable to tolerate her usual level of activity/exercise; reporting that she was typically able to run ten miles without problems, but, recently, she could run only a mile and developed heart palpitations (heart pounding) and dizziness if she walked a block. She denied spinning sensation, syncope, and depression. The participant also reported having normal thyroid test and other blood work. Treatment for the event included formoterol inhaler and meclizine additionally, the participant was treated with a course of amoxicillin for a sinus infection.

On 18 Nov 2020, electrocardiogram was normal. Additional diagnostic test results included magnetic resonance imaging of brain showed no acute changes with cerebrospinal fluid collection at the right cerebellomedullary angle suggestive of an arachnoid cyst; chest x-ray was normal; thyroid-stimulating hormone, complete blood count, chemistries, aspartate aminotransferase, alanine aminotransferase, and D-dimer were normal. Hallpike maneuver was negative; no nystagmus (she was briefly dizzy), blood pressure 118/79 mmHg and pulse 71 beats per minute while lying and blood pressure 111/77 mmHg and pulse 76 beats per minute while standing. The participant reported to have intermittent dizziness and vertigo often precipitated by exercise.

She was referred to get a Holter monitor and cardiology evaluation by her doctor, with encouragement from the Investigator to pursue the referral to cardiology and additional recommendation for neurology evaluation as she continues to have symptoms of fatigue and dizziness that limit her exercise and activities. The Investigator stated that the participant's symptoms of fatigue, dizziness and palpitations were possibly related to the study product based on a temporal relationship. The Sponsor assessed the event as unrelated to study product due to the presence of multiple confounders including concurrent sinus infection and history of hypothyroidism as more plausible explanations for the participant's symptoms.

Action taken with the study drug was not applicable in response to the event as the participant received both doses of study drug.