

Participant ID	MCN
US3752245	(b) (6)
Preferred Terms:	Facial Paralysis
Treatment Assignment:	mRNA-1273
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A 67 year-old female, Asian participant experienced a serious adverse event of facial paralysis (verbatim term Bell's Palsy). The participant's medical history included colonoscopy X2, hyperlipidemia, breast biopsy (unknown if benign or malignant) X2, appendectomy, joint pain (location and associated medical condition unknown), tendinitis bilateral wrists, penicillin allergy, naproxen allergy, latex allergy, previous cerebrovascular accident, asthma, diabetes mellitus type II, urinary incontinence, depression, seasonal allergies, obstructive sleep apnea, tubal ligation, and tonsillectomy. The participant received the first dose of blinded study drug on 25 Aug 2020 in the left arm. The participant's last dose of study drug prior to event onset was on 06 Oct 2020 in the left arm. On 06 Nov 2020, the participant experienced bell's palsy assessed as grade 4 severity. The side of the face affected was not reported. She was hospitalized to rule out stroke. Her computerized tomography scan (CT scan) results were inconclusive. According to the participant, her magnetic resonance imaging (MRI) showed no evidence of current, acute stroke but did show possible stroke in the past. Treatment for the event included valaciclovir and methylprednisolone, and, acetylsalicylic acid, clopidogrel, and enoxaparin sodium for prevention of stroke. The investigator reported that the participant will follow-up with her primary care physician to determine long-term management. On 07 Nov 2020, the participant was discharged from the hospital and the event was considered resolving. Action taken with study drug dosing in response to the event was not applicable as the participant had already received both scheduled doses.

Subject ID	MCN
US3182040	N/A
Preferred Terms:	Facial paralysis
Treatment Assignment:	Placebo
Relationship	Not related
Baseline SARS-CoV-2	Negative

A 52 year-old White male with history of hypertension, moderate asthma, seasonal allergies, osteoarthritis, acid reflux reported facial paralysis (verbatim term Bell’s palsy) on 13 August. The participant received placebo dose 1 on 28 Jul 2020 in the left arm and dose 2 on 28 August in the left arm. On 13 August the participant reported Bell’s palsy as a medically-attended adverse event. The side of the face involved was not reported. The event was assessed by the investigator as moderately severe, non-serious and not related to study product. Valacyclovir and prednisone were prescribed. At the time of this report the event was considered recovering/resolving.

Participant ID	MCN
US3382271	N/A
Preferred Terms:	Facial paralysis
Treatment Assignment:	mRNA-1273
Relationship	Not Related
Baseline SARS-CoV-2	Negative

A 72 year old female, Asian participant experienced a non-serious event of facial paralysis (verbatim term Bell’s palsy) on Day 53 post Dose 1. Her medical history included hysterectomy, left oophorectomy, bilateral cataract extraction with intraocular lens implants, bilateral cataracts, uterine fibroids, seasonal allergies, benign thyroid tumor, thyroidectomy, and tinnitus. Her concomitant medications included levothyroxine, gabapentin, cephalexin, augmentin, prednisone, and valacyclovir. On 18 Sep 2020, the participant received the first dose of mRNA-1273 in the left arm. On 14 Oct 2020, she received her second dose of mRNA-1273 in the left arm. On 04 Nov 2020, the participant experienced facial paralysis. The side of the face that was involved was not reported. At the time of the report, the event was considered ongoing, non-serious and Grade 2 (moderate) in intensity. Action taken with study drug dosing in response to the event was not applicable as the participant had already received both scheduled doses.

Subject ID	MCN
US3432056	N/A
Preferred Terms:	Facial paralysis
Treatment Assignment:	mRNA-1273
Relationship	Not related
Baseline SARS-CoV-2	Negative

This 30 year old white female with history of headaches, migraines, ocular migraines and depression reported facial paralysis (verbatim term Bell’s palsy).

The participant received mRNA-1273 dose 1 on 7 August 2020 in the left arm and dose 2 on 8 Sept in the left arm. On 9 September, the participant reported an upper respiratory tract infection as a medically-attended adverse event, mild in severity, non-serious and not-related to study product. The event was resolved on 6 October. She reported Bell’s palsy on 6 Oct as a medically-attended adverse event. The side of the face involved was not reported. Prednisone was prescribed as a treatment. The event was assessed by the investigator as moderately severe, non-serious and not related to study product. In October 2020, the event was considered recovered/resolved.