SUMMARY OF THE RISK MANAGEMENT PLAN

For

mNEXSPIKE (SARS-CoV-2 mRNA)

COVID-19-mRNA Vaccine

Marketing Authorization Number 70272

Dispersion for injection

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Table of Contents

List of Tables **3**

List of Abbreviations **4**

Overview **5**

I The Medicine and What it is Used for **6**

II Risks Associated With the Medicine and Activities to Minimise or Further Characterise These Risks **6**

II.A List of Important Risks and Missing Information 7

II.B Summary of Important Risks 8

II.C Post-Authorisation Development Plan 11

II.C.1 Studies Which are Conditions of the Marketing Authorisation 11

II.C.2 Other Studies in Post-Authorisation Development Plan 11

List of Tables

Table 1: List of Important Risks and Missing Information 7
Table 2: Important Potential Risk: Myocarditis 8
Table 3: Important Potential Risk: Pericarditis 9
Table 4: Missing information: Use in pregnancy 10
Table 5: Other Studies in the Post-Authorisation Development Plan 11

List of Abbreviations

Acronym	Definition
COVID-19	COVID-19 disease caused by the 2019 coronavirus
CoV	Coronavirus
EMA	European Medicine Agency
EPAR	European Public Assessment Report
MCM	Major congenital malformation
mRNA	Messenger ribonucleic acid
PL	Patient leaflet
PSUR	Periodic safety update report
RMP	Risk management plan
SARS	Severe acute respiratory syndrome
SmPC	Summary of Product Characteristics
US	United States

Overview

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary of mNEXSPIKE is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of mNEXSPIKE in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedicinfo-pro.ch) approved and authorized by Swissmedic. Moderna Switzerland GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of mNEXSPIKE.

Summary of Risk Management Plan for mNEXSPIKE dispersion for injection in pre-filled syringe (COVID-19 mRNA Vaccine)

This is a summary of the risk management plan (RMP) for mNEXSPIKE. The RMP details important risks of mNEXSPIKE, how these risks can be minimised, and how more information will be obtained about mNEXSPIKE's risks and uncertainties (missing information).

mNEXSPIKE's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how mNEXSPIKE should be used.

This summary of the RMP for mNEXSPIKE should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of mNEXSPIKE's RMP.

I The Medicine and What it is Used for

mNEXSPIKE is authorised for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. The active substance is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 circulating variant.

Further information about the evaluation of mNEXSPIKE's benefits can be found in mNEXSPIKE's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/mnexspike

II Risks Associated With the Medicine and Activities to Minimise or Further Characterise These Risks

Important risks of mNEXSPIKE, together with measures to minimise such risks and the proposed studies for learning more about mNEXSPIKE's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (eg, with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment - so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of mNEXSPIKE is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of mNEXSPIKE are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of mNEXSPIKE. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (eg, on the long-term use of the medicine).

Table 1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important Identified Risks	None
Important Potential Risks	Myocarditis Pericarditis
Missing Information	Use in pregnancy

II.B Summary of Important Risks

Table 2: Important Potential Risk: Myocarditis

Important Potential Risk: Myocarditis	
Evidence for linking the risk to the medicine	Myocarditis can be caused by a variety of factors; the most common aetiology is viral infection. Myocarditis has not been causally associated with mNEXSPIKE and the risk is anticipated to be lower than approved COVID-19 vaccines as it does not include the furin cleavage site, potentially eliminating circulating spike protein antigen that may interact with heart tissue. In Study mRNA-1283-P301, there were no myocarditis events in either mRNA-1283 or mRNA-1273 vaccinated participants up to the data cutoff (23 Feb 2024). In Study mRNA-1283-P301-Japan, no events of myocarditis were reported in either vaccine group up to the data cutoff (02 May 2024). Likewise in studies mRNA-1283-P201 and mRNA-1283-P101, no events of myocarditis were observed throughout the studies.
Risk factors and risk groups	Acute myocarditis is overall more common in men than in women (Kytö et al 2013). The incidence rate occurs with 2 peaks: the highest in those under one year old with both genders combined (Vasudeva et al 2021) and young males aged 16 to <40 years old (Vasudeva et al 2021; Kytö et al 2013).
Risk minimisation measures	Routine risk minimisation measures: Warning for healthcare professionals to be aware that an increased risk of myocarditis and pericarditis has been observed following vaccination with some other COVID-19 vaccines and to be alert to the signs and symptoms of myocarditis and pericarditis in SmPC Section 4.4 Warning for healthcare professionals to instruct vaccine recipients (including parents or caregivers) to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis in SmPC Section 4.4 Warning for users to be aware that cases of myocarditis and pericarditis (inflammation of the heart muscle or the membrane around the heart) have been reported for other authorised COVID-19 vaccines in PL Section 2 Warning for users to be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, following vaccination and to seek immediate medical attention should these occur in PL Section 2 Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: mRNA-1283-P901 mRNA-1283-P904 mRNA-1283-P906 See Section II.C of this summary for an overview of the post-authorisation development plan.

Table 3: Important Potential Risk: Pericarditis

Important Potential Risk: Pericarditis	
Evidence for linking the risk to the medicine	Pericarditis can be caused by a variety of factors; the most common aetiology is viral infection. Pericarditis has not been causally associated with mNEXSPIKE and the risk is anticipated to be lower than approved COVID-19 vaccines as it does not include the furin cleavage site, potentially eliminating circulating spike protein antigen that may interact with heart tissue. In Study mRNA-1283-P301, there were no pericarditis events in either mRNA-1283 or mRNA-1273 vaccinated participants within 28 days post injection. Up to the data cutoff (23 Feb 2024), 1 event of suspected pericarditis was reported in the mRNA-1273 group that was assessed as not related to study injection; no pericarditis events were observed in the mRNA-1283 group. In Study mRNA-1283-P301-Japan, no events of pericarditis were reported in either vaccine group up to the data cutoff (02 May 2024). In studies mRNA-1283-P201 and mRNA-1283-P101, no events of pericarditis were observed throughout the studies.
Risk factors and risk groups	Acute pericarditis is overall more common in men than in women. However, the gender difference is reduced with advancing age and became nominal in persons aged >65 years (Kytö et al 2014). In males, the incidence rate of acute pericarditis declines between 16 to 45 years followed by an increase in older individuals aged >50 years (Kytö et al 2014). In females, the incidence rate of acute pericarditis gradually increases with age, with a peak in the population aged 65 to 74 years (Kytö et al 2014; Kumar et al 2016).
Risk minimisation measures	Routine risk minimisation measures: Warning for healthcare professionals to be aware that an increased risk of myocarditis and pericarditis has been observed following vaccination with some other COVID-19 vaccines and to be alert to the signs and symptoms of myocarditis and pericarditis in SmPC Section 4.4 Warning for healthcare professionals to instruct vaccine recipients (including parents or caregivers) to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis in SmPC Section 4.4 Warning for users to be aware that cases of myocarditis and pericarditis (inflammation of the heart muscle or the membrane around the heart) have been reported for other authorised COVID-19 vaccines in PL Section 2 Warning for users to be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, following vaccination and to seek immediate medical attention should these occur in PL Section 2 Additional risk minimisation measures: None.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: mRNA-1283-P901 mRNA-1283-P906 See Section II.C of this summary for an overview of the post-authorisation development plan.

Table 4: Missing information: Use in pregnancy

Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.6 SmPC Section 5.3 Precautionary guidance to avoid the use of mNEXSPIKE during pregnancy in SmPC Section 4.6 Guidance for the user to tell their doctor, nurse or pharmacist if they are pregnant or think they may be pregnant before they receive this vaccine in PL Section 2 Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: mRNA-1283-P902 See Section II.C of this summary for an overview of the post-authorisation development plan.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of mNEXSPIKE.

II.C.2 Other Studies in Post-Authorisation Development Plan

The following studies are considered ongoing and/or planned additional pharmacovigilance activities:

Table 5: Other Studies in the Post-Authorisation Development Plan

Study Title and Number ***Status***	**Purpose of the Study**
mRNA-1283-P901 Post-marketing safety of the mRNA-1283 vaccine in the United States *Planned*	Primary Objectives: • Estimate the incidence of myocarditis and pericarditis among recipients of mRNA-1283 and among individuals who have not received the prior seasonal formulation of COVID-19 vaccine within the past 90 days or the same seasonal formulation previously • Compare the risk of myocarditis and pericarditis among the recipients of mRNA-1283 with the risk among individuals who have not received the prior seasonal formulation of COVID-19 vaccine within the past 90 days or the same seasonal formulation previously
mRNA-1283-P902 An observational cohort study to assess maternal and infant outcomes following exposure to mRNA-1283 during pregnancy *Planned*	Primary Objectives: • Describe the utilisation of the mRNA-1283 vaccine in routine clinical practice and estimate incidence rates of pregnancy complications (gestational hypertensive disorders and gestational diabetes), adverse pregnancy outcomes (medically attended spontaneous abortion, stillbirth, and preterm birth), and infant major congenital malformations among mRNA-1283 vaccine recipients using large-scale administrative claims data in the US. • Upon accrual of a sufficient number of exposed pregnancies: o Assess whether exposure to mRNA-1283 during pregnancy is associated with an increased rate of pregnancy complications. o Assess whether exposure to mRNA-1283 during pregnancy is associated with an increased rate of adverse pregnancy outcomes. o Assess whether exposure to mRNA-1283 during pregnancy is associated with an increased prevalence of infant MCM.
mRNA-1283-P904 Long-term outcomes of myocarditis following administration of the mRNA-1283 vaccine *Planned*	Primary Objectives: • Characterise the presentation and clinical course of vaccine-associated myocarditis • Characterise potential long-term outcomes following vaccine-associated myocarditis
mRNA-1283-P906 Post-marketing safety of the mRNA-1283 vaccine in Europe	Primary Objectives: • Monitor the distribution of mRNA-1283 in Europe.

Study Title and Number ***Status***	**Purpose of the Study**
Planned	• Describe the uptake of mRNA-1283, characterise vaccine recipients, and estimate the incidence of myocarditis and pericarditis among them. • Compare the risk of myocarditis and pericarditis among the recipients of mRNA-1283 with the risk among individuals who have not received a COVID-19 vaccine within the past 90 days.

Abbreviations: COVID-19 = coronavirus disease 2019; MCM = major congenital malformation; mRNA = messenger ribonucleic acid; SARS-CoV-2 = severe acute respiratory syndrome coronavirus-2; US = United States.