Exhibit

Moderna mRNA-1273 (Spikevax) Nonclinical Program

2.4.2. PHARMACOLOGY

Table 1 summarizes the nonclinical pharmacology program for mRNA-1273. Pharmacology results are fully summarized in Module 2.6.2.

Table 1: Summary of Pharmacology Program for mRNA-1273

Study Type/Description	Test Article Dose (µg)	Species, Strain	Method of Administration; Immunization Schedule	GLP	Report Number
Primary Pharmacology					
Evaluation of in vitro expression of SARS-CoV-2 mRNA and in vivo expression of mRNA-1273	SARS-CoV-2 S-2P mRNA: 0.003125 through 0.2 µg mRNA-1273: 2 or 10 µg	HEK293T cells BALB/c mice	In vitro transfection In vivo IM; single injection	No	MOD-4117.1273
Evaluation of immunogenicity, protective capacity, and safety in young mice	mRNA-1273: 0.01, 0.1, 1 or 10 µg SARS-CoV-2 S-2P: 0.01, 0.1, or 1 µg (+ SAS-adjuvant)	Mouse (young), BALB/cJ, C57BL/6J, B6C3F1/J	IM; prime only prime/boost (3-week interval) prime/boost (4-week interval)	No	VRC01
Immunization and protein restimulation in young BALB/c mice with enhanced respiratory disease endpoint monitoring	mRNA-1273: 1 or 10 µg SARS-CoV-2 S-2P: 10 µg (+ alum)	Mouse (young), BALB/c	IM; prime/boost (2-week interval)	No	MOD-3937
Immunogenicity and determination of titer dynamic range in young BALB/c mice	mRNA-1273: 0.0025 through 20 µg	Mouse (young), BALB/c	IM; prime/boost (3-week interval)	No	MOD-3938/ MOD-3940
Immunogenicity and characterization of cellular response in young BALB/cJ mice	mRNA-1273: 0.1, 1, or 10 µg SARS-CoV-1 DIV: 0.2 or 1 µg (+ alum) CDS: 0.2 or 1 µg (+ alum)	Mouse (young), BALB/c	IM; prime/boost (3-week interval)	No	VRC05
Efficacy and enhanced respiratory disease in aged BALB/c mice	mRNA-1273: 0.1 or 1 µg SARS-CoV-1 DIV: 0.1 µg (+ alum)	Mouse (aged), BALB/c	IM; prime/boost (3-week interval)	No	VRC02

Obtained via FOIA by Judicial Watch, Inc.

ModernaTX, Inc.
2.4 Nonclinical Overview
mRNA-1273

Study Type/Description	Test Article Dose (µg)	Species, Strain	Method of Administration; Immunization Schedule	GLP	Report Number
Primary Pharmacology					
Five-week (2 doses: prime/boost) repeat-dose immunogenicity with safety endpoints	mRNA-1273: 0, 30, 60, or 100 µg	Rat, Sprague Dawley	IM; prime/boost (3-week interval)	No	2308-123
Protection from WT SARS-CoV-2 in hamsters using optimal and suboptimal doses	mRNA-1273: 1, 5, or 25 µg	Hamster, golden Syrian	IM; prime/boost (3-week interval)	No	UTMB01
Immunogenicity and protective efficacy in NHPs	mRNA-1273: 10 or 100 µg	NHP, rhesus macaque (Indian-origin)	IM; prime/boost (4-week interval)	No	VRC04
Evaluation of immunogenicity and efficacy from expanded dose range in NHPs	mRNA-1273: 2.5, 30, or 100 µg	NHP, rhesus macaque (Indian-origin)	IM; prime/boost (4-week interval)	No	VRC07

Abbreviations: alum = aluminum hydroxide; CDS = conformationally disrupted severe acute respiratory syndrome coronavirus-2 S protein; GLP = Good Laboratory Practice; IM = intramuscular; mRNA = messenger RNA; NHP = nonhuman primate; SARS-CoV-1 DIV = double-inactivated severe acute respiratory syndrome coronavirus-1; SARS-CoV-2 = 2019 novel coronavirus; S-2P = spike protein modified with 2 proline substitutions within the heptad repeat 1 domain; SAS = Sigma Adjuvant System®; WT = wild-type.

All Primary Pharmacology studies conducted with mRNA-1273 (Spikevax) were non-GLP

2.4.3. PHARMACOKINETICS AND TISSUE DISTRIBUTION

Table 2 lists the nonclinical pharmacokinetics and tissue distribution study with mRNA-1647 in support of the development of mRNA-1273. Biodistribution results are fully summarized in Module 2.6.4.

Table 2: Summary of Pharmacokinetics Program for mRNA-1273

Study Type	Test Article	Species, Strain	Method of Administration, Dose	GLP	Report Number
Single-dose tissue distribution study	mRNA-1647[a]	Rat, Sprague Dawley	IM injection dose of 100 µg on Day 1	No	5002121 Amendment 1

Abbreviations: CMV = cytomegalovirus; gB = glycoprotein B; gH = glycoprotein H; gL = glycoprotein L; GLP = Good Laboratory Practice; IM = intramuscular; mRNA = messenger RNA.

[a] mRNA-1647 contains 6 mRNAs that encode the full-length CMV gB and the pentameric gH/gL/UL128/UL130/UL131A glycoprotein complex. The 6 mRNAs are combined at a target mass ratio of 1:1:1:1:1:1 in a mixture of 4 lipids (SM-102, PEG2000-DMG, cholesterol, and DSPC) and formulated in 93 mM Tris, 60 mM NaCl, and 7% PG.

Biodistribution studied with non-representative product and non-GLP

charles river

NON-GLP FINAL REPORT AMENDMENT NO. 01

Test Facility Study No. 5002121

A Single Dose Intramuscular Injection Tissue Distribution Study of mRNA-1647 in Male Sprague-Dawley Rats

Biodistribution studied in non-representative test article, non-GLP and in male animals only

SPONSOR:
Moderna Therapeutics, Inc.
200 Technology Square, Third Floor
Cambridge, MA 02139
USA

TEST FACILITY:
Charles River Laboratories Montreal ULC
Sherbrooke Site (CR SHB)
1580 Ida-Metivier
Sherbrooke, QC J1E 0B5
Canada

2.4.4. TOXICOLOGY

Table 3 summarizes the nonclinical toxicology program used in support of the development of mRNA-1273. Toxicology results are fully summarized in Module 2.6.6.

Table 3: Summary of Toxicology Program for mRNA-1273

Study Type	Test Article	Species, Strain	Method of Administration; Dose	GLP	Report Number
Repeat-Dose Toxicity					
1-month (3 doses) repeat-dose study with 2-week recovery	mRNA-1706[a]	Rat, Sprague Dawley	IM; 0, 13, 65, 129 µg/dose[b] (Days 1, 15, 29)	Yes	5002045
1-month (3 doses) repeat-dose study with 2-week recovery	mRNA-1706[a]	Rat, Sprague Dawley	IM; 0, 10, 50, 100 µg/dose (Days 1, 15, 29)	Yes	5002231
1-month (3 doses) repeat-dose study with 2-week recovery	mRNA-1653[c]	Rat, Sprague Dawley	IM; 0, 10, 50, 150 µg/dose (Days 1, 15, 29)	Yes	5002033
1-month (3 doses) repeat-dose study with 2-week recovery	mRNA-1893[d]	Rat, Sprague Dawley	IM; 0, 10, 30, 96 µg/dose (Days 1, 15, 29)	Yes	5002400
6-week (4 doses) repeat-dose study with 2-week recovery	mRNA-1647[e]	Rat, Sprague Dawley	IM; 0, 8.9, 27, 89 µg/dose[f] (Days 1, 15, 29, 43)	Yes	5002034
6-week (4 doses) repeat-dose study with 2-week recovery	mRNA-1443[g]	Rat, Sprague Dawley	IM; 0, 9.6, 29, 96 µg/dose[h] (Days 1, 15, 29, 43)	Yes	5002158
In Vitro Genotoxicity					
Bacterial reverse mutation test	SM-102	*Salmonella typhimurium, Escherichia coli*	Incubation for 67 hours 29 minutes with 0, 1.58, 5.0, 15.8, 50, 158, 500, 1581, 5000 µg/plate SM-102 with or without supplemented rat liver fraction	Yes	9601567
Bacterial reverse mutation test	PEG2000-DMG (b) (4)	*Salmonella typhimurium, Escherichia coli*	Incubation for 67 h and 57 min with 0, 1.58, 5.0, 15.8, 50, 158, 500, 1581, 5000 µg/plate PEG2000-DMG with or without supplemented rat liver fraction	Yes	9601035
Mammalian cell micronucleus test	SM-102	Human peripheral blood lymphocytes	Incubation for 4 and 24 hours with 0, 163, 286, 500 µg/mL SM-102 with or without supplemented rat liver fraction	Yes	9601568
Mammalian cell micronucleus test	PEG2000-DMG (b) (4)	Human peripheral blood lymphocytes	Incubation for 4 h and/or 24 hours with 0, 0, 53.3, 93.3, 163, 286, 500 µg/mL PEG2000-DMG with or without supplemented rat liver fraction	Yes	9601036
In Vivo Genotoxicity					

Toxicology studied with non-representative test articles, i.e. **not** mRNA-1273 (Spikevax)

Study Type	Test Article	Species, Strain	Method of Administration; Dose	GLP	Report Number
In vivo mammalian erythrocyte micronucleus test	mRNA-1706[a]	Rat, Sprague Dawley	Single IV; 0, 0.6/6.2 (F), 1.3/13.5, 2.6/27.0, 5.2/54.1 (M) mg/kg mRNA-1706/SM-102[j, k]	Yes	9800399
In vivo mammalian erythrocyte micronucleus test	NPI luciferase mRNA[l]	Rat, Sprague Dawley	Single IV; 0, 0.32/6.0, 1.07/20, 3.21/60 mg/kg NPI luciferase mRNA/SM-102	No	AF87FU.125012 NGLPICH.BTL
Reproductive and Developmental Toxicity					
Combined developmental and perinatal/postnatal developmental and reproductive toxicity study	mRNA-1273[m]	Rat, Sprague Dawley	IM; 100 µg/dose (Study Days 1 and 15 [28 and 14 days prior to mating, respectively] and Gestation Days 1 and 13)	Yes	20248897
Other Toxicology					
5-week (2 doses) repeat-dose immunogenicity and toxicity study	mRNA-1273[n]	Rat, Sprague Dawley	IM; 0, 30, 60, 100 µg/dose (Days 1 and 22)	No	2308-123

Abbreviations: CMV = cytomegalovirus; CoV = coronavirus; F = female; gB = glycoprotein B; gH = glycoprotein H; gL = glycoprotein L; GLP = Good Laboratory Practice; h = hour; IM = intramuscular; IV = intravenous; M = male; min = minute; mRNA = messenger RNA; NPI = nascent peptide imaging; pp65 = phosphoprotein 65; prME = pre-membrane and envelope; S-2P = spike protein modified with 2 proline substitutions within the heptad repeat 1 domain; SARS-CoV-2 = 2019 novel coronavirus; SoA = summary of analysis.

[a] mRNA-1706 contains a single mRNA sequence that encodes the prME structural proteins of Zika virus combined in a mixture of 4 lipids (SM-102, PEG2000-DMG, cholesterol, and DSPC) and formulated in 20 mM Tris, 8% sucrose, pH 7.4.

[b] The original dose levels selected were 0, 10, 50, and 100 µg/dose, respectively (SoA issued on 11 October 2016). The calculated dose levels were revised based on the updated concentration reported for mRNA-1706 Lot No. MTDP16064 (SoA issued on 03 May 2017). The change in the reported mRNA content for mRNA-1706 was 29%.

[c] mRNA-1653 contains 2 distinct mRNA sequences that encode the full-length membrane-bound fusion proteins of human metapneumovirus and parainfluenza virus type 3. The 2 mRNAs are combined at a target mass ratio of 1:1 in a mixture of 4 lipids (SM-102, PEG2000-DMG, cholesterol, and DSPC) and formulated in 93 mM Tris, 7% PG, 1 mM DTPA, pH 7.4.

[d] mRNA-1893 contains a single mRNA sequence that encodes the prME structural proteins of Zika virus in a mixture of 4 lipids (SM-102, PEG2000-DMG, cholesterol, and DSPC) and formulated in 100 mM Tris, 7% PG, 1 mM DTPA, pH 7.5.

[e] mRNA-1647 contains 6 mRNAs that encode the full-length CMV gB and the pentameric gH/gL/UL128/UL130/UL131A glycoprotein complex. The 6 mRNAs are combined at a target mass ratio of 1:1:1:1:1:1 in a mixture of 4 lipids (SM-102, PEG2000-DMG, cholesterol, and DSPC) and formulated in 93 mM Tris, 60 mM NaCl, and 7% PG.

[f] The original dose levels selected were 0, 10, 30, and 100 µg/dose, respectively (SoA issued on 16 Mar 2017). The calculated dose levels were revised based on the updated concentration reported for mRNA-1647 Lot No. MTDP17015 (SoA issued on 31 May 2017). The change in the reported mRNA content for mRNA-1647 was –11%.

Toxicology studied with non-representative test articles, i.e. **not** mRNA-1273 (Spikevax)

Non-GLP