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List of Abbreviations

Abbreviation	Definition
AUC	area under the concentration versus time curve
$AUC_{(0-t)}$	area under the concentration versus time curve from the start of dose administration to the time after dosing at which the last quantifiable concentration was observed
bDNA	branched DNA
C_{max}	maximum plasma concentration
CoV	coronavirus
DSPC	1,2-distearoyl-sn-glycero-3-phosphocholine
gB	glycoprotein B
gH	glycoprotein H
gL	glycoprotein L
GLP	Good Laboratory Practice
IM	intramuscular(ly)
LLOQ	lower limit of quantitation
LNP	lipid nanoparticle
mRNA	messenger RNA
PEG2000-DMG	1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000
PG	propylene glycol
PK	pharmacokinetic
S	spike
S-2P	spike protein modified with 2 proline substitutions within the heptad repeat 1 domain
SARS-CoV-2	2019 novel coronavirus
SM-102	heptadecan-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate
$T_{1/2}$	half-life
Tris	tris(hydroxymethyl)aminomethane
T_{max}	time to peak (maximum) plasma concentration

2.6.4.1 BRIEF SUMMARY

ModernaTX, Inc. (Sponsor) has developed mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2). mRNA-1273 contains a single mRNA that encodes the full-length spike (S) protein modified with 2 proline substitutions within the heptad repeat 1 domain (S-2P) to stabilize the S protein into the prefusion conformation. The mRNA is combined in a mixture of 4 lipids common to the Sponsor's mRNA vaccine platform: SM-102, cholesterol, DSPC, and PEG2000-DMG.

The results of a biodistribution study of mRNA-1647 support the development of mRNA-1273. mRNA-1647 is a novel mRNA-based cytomegalovirus vaccine that contains 6 distinct mRNA sequences (1 that encodes the full-length cytomegalovirus glycoprotein B [gB], and 5 that encode the pentameric glycoprotein H [gH]/glycoprotein L [gL]/UL128/UL130/UL131A glycoprotein complex) combined at a target mass ratio of 1:1:1:1:1:1 in the Sponsor's standard proprietary SM-102–containing LNPs.

The biodistribution of mRNA-1647 was evaluated in a non-Good Laboratory Practice (GLP), single-dose, intramuscular (IM) injection study in Sprague Dawley rats. The objectives of this study were to determine the tissue distribution and pharmacokinetic (PK) characteristics of mRNA-1647 following IM administration. The biodistribution of mRNA-based vaccines in LNPs is predicted to be driven by the LNP characteristics. Therefore, mRNAs that are within an LNP of the same composition (eg, mRNA-1273 and mRNA-1647) are expected to distribute similarly.

Concentrations for all 6 mRNA-1647 constructs, gB, gH, gL, UL128, UL130, and UL131A, were detectable in plasma and tissues in a 1:1:1:1:1:1 ratio. After a single IM dose in male rats, the time after dosing at which the maximum concentration was observed in plasma (T_{max}) was 2 hours for all constructs and was followed by a rapid elimination phase, with a half-life ($T_{1/2}$) estimated to range from 2.7 to 3.8 hours. The maximum plasma concentration (C_{max}) ranged from 1.60 to 2.30 ng/mL, and the area under the concentration versus time curve (AUC) from the start of dose administration to the time after dosing at which the last quantifiable concentration was observed ($AUC_{[0\text{-}t]}$) ranged from 22.7 to 25.5 ng × h/mL.

Concentrations for all 6 mRNA-1647 constructs were detected at levels above the lower limit of quantitation (LLOQ) in most tissues analyzed, except for the kidney, where all levels were below the LLOQ. For highly exposed tissues (injection site [muscle], lymph nodes [proximal and

distal], and spleen), the C_{max} was observed between 2 and 24 hours post-dose. The $T_{1/2}$ was calculated using the average tissue $T_{1/2}$ values for all 6 constructs. The results were 14.9 hours for injection site (muscle), 34.8 hours for proximal (popliteal) lymph nodes, 31.1 hours for distal (axillary) lymph nodes, and 63.0 hours for spleen.

As observed with other IM delivered vaccines, the highest mRNA concentrations were observed at the injection site followed by the proximal (popliteal) and distal (axillary) lymph nodes, consistent with distribution via the lymphatic system. These tissues, as well as spleen and eye, had tissue-to-plasma AUC ratios > 1.0.

Overall, only a relatively small fraction of the administered mRNA-1647 dose distributed to distant tissues, and the mRNA constructs did not persist past 1 to 3 days in tissues other than muscle (injection site), proximal popliteal and distal axillary lymph nodes, and spleen, in which the average $T_{1/2}$ values for all constructs ranged from 14.9 to 63.0 hours.. The completed nonclinical PK and biodistribution study is presented in Table 1.

Table 1: Nonclinical Biodistribution Study Supporting Development of mRNA-1273

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

Abbreviations: CMV = cytomegalovirus; gB = glycoprotein B; gH = glycoprotein; 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.

2.6.4.2 METHODS OF ANALYSIS

The procedure followed during the course of this study, along with the assay acceptance criteria, was detailed in a bioanalytical protocol. The LLOQs for plasma and tissues was set at 0.05 ng/mL for the gB and UL130 constructs and 0.01 ng/mL for the gH, gL, UL128, and UL131A constructs. Samples were analyzed in duplicate. Details on how biological samples were collected and processed are provided in the study report (Report 5002121 Amendment 1 Section 4.12).

Samples were analyzed for all 6 mRNA constructs (gB, gH, gL, UL128, UL130, and UL131A) present in mRNA-1647. To quantify these multiple constructs in mRNA-1647, a multiplex branched DNA (bDNA) assay was used. This assay is a hybridization-based method that combines multi-analyte profiling beads and bDNA signal amplification to enable the detection and quantitation of multiple RNA targets simultaneously. After preparation, a sample is combined with an array of fluorescent microspheres (capture beads) and probe sets specific for each RNA molecule of interest and allowed to incubate overnight. The capture beads are used as a support to capture RNA molecules, and the probe sets are used to quantify multiple target-specific RNA molecules within a single sample. Signal amplification is mediated by DNA amplification molecules that hybridize to one of the synthetic probes within each RNA-specific probe set. The capture beads are hybridized with pre-amplifier, amplifier, and label probe solutions. The label probes bind to streptavidin-conjugated R-phycoerythrin, and the resulting fluorescence signal associated with individual capture beads is read on a Luminex® flow cytometer. The signal is reported as the median fluorescence intensity and is proportional to the number of target RNA molecules present in the sample.

2.6.4.3 ABSORPTION

No absorption studies with mRNA-1273 have been performed.

2.6.4.4 DISTRIBUTION

2.6.4.4.1 Tissue Distribution Studies

The objective of this non-GLP study was to determine the tissue distribution of mRNA-1647 when given once by IM injection to rats. The PK characteristics of mRNA-1647 were determined in plasma and tissue. A group of 35 male Sprague Dawley rats was given a single IM injection of 100 µg of mRNA-1647 in a dose volume of 200 µL (dose concentration of 0.5 mg/mL) on Day 1. Subgroups of 5 rats each were sacrificed pre-dose and 2, 8, 24, 48, 72, and 120 hours after IM dosing. Blood and tissues were collected and processed for quantitation of the 6 mRNA constructs (gB, gH, gL, UL128, UL130, and UL131A) present in mRNA-1647 using a qualified bDNA multiplex method (Section 2.6.4.2). The overall design of this study is presented in Table 2.

Table 2: A Single-Dose IM Pharmacokinetic and Biodistribution Study of mRNA-1647 in Sprague Dawley Rats

Group Number	Test Article (Method of Administration)	Species/ Strain	Number of Animals/Sex	Dose Level (µg)	Dose Volume (µL)	Dose Concentration (mg/mL)	Sample Collection Time Points (h)
1	mRNA-1647 (single IM injection)	Rats/ Sprague Dawley	35/male	100	200	0.5	0 (pre-dose), 2, 8, 24, 48, 72, and 120

Abbreviations: IM = intramuscular.
Source: Report 5002121 Amendment 1 (Text Table 3 and Text Table 4).

No quantifiable concentrations for any of the mRNA constructs were observed in plasma or tissue in pre-dose samples, with the exception of 2 plasma samples for which the gH construct concentration was slightly above the LLOQ. For all 6 mRNA constructs present in mRNA-1647, post-dose levels were detectable in plasma and tissues in a 1:1:1:1:1:1 ratio. Mean plasma concentrations were quantifiable up to 24 hours with an interanimal coefficient of variation from 21.8% and 79.8%. The only quantifiable plasma samples beyond 24 hours were 6 gH constructs that were slightly above the LLOQ.

After a single IM dose in male rats, the T_{max} for all 6 mRNA constructs was 2 hours, followed by a rapid elimination phase. Mean concentrations became undetectable for all constructs after 24 hours with the exception of gH, which was detectable up to the last time point of 120 hours. Due to the lack of a distinct elimination phase, the $T_{1/2}$ of the mRNA constructs could not be calculated; however, the $T_{1/2}$ was estimated to range from 2.7 to 3.8 hours. The C_{max} and $AUC_{(0-t)}$ ranged from 1.60 to 2.30 ng/mL and from 22.7 to 25.5 ng × h/mL, respectively (Table 3).

Table 3: Plasma Pharmacokinetic Parameters for a Single IM Dose of 100 µg of mRNA-1647 in Male Sprague Dawley Rats

Matrix	Construct	T_{max} (h)[a]	C_{max} (ng/mL)[a]	$AUC_{(0-t)}$ (ng × h/mL)[a]	$T_{1/2}$ (h)[b]
Plasma	gB	2.0	2.02 ± 0.181	22.7 ± 3.77	NC
	gH	2.0	1.91 ± 0.187	24.9 ± 4.49	NC
	gL	2.0	1.74 ± 0.177	23.4 ± 4.07	NC
	UL128	2.0	1.66 ± 0.151	24.1 ± 4.44	NC
	UL130	2.0	2.30 ± 0.621	25.5 ± 4.65	NC
	UL131A	2.0	1.60 ± 0.153	24.8 ± 4.59	NC

Abbreviations: gB = glycoprotein B; gH = glycoprotein H; gL = glycoprotein L; IM = intramuscular; NC = not calculable (insufficient data points above the lower limit of quantification).

[a] T_{max} data reported as the mean; C_{max} and $AUC_{(0-t)}$ data reported as the mean ± standard error.

[b] Due to the lack of a distinct elimination phase, the $T_{1/2}$ of the mRNA constructs could not be calculated; however, the $T_{1/2}$ was estimated to range from 2.7 to 3.8 hours.

Source: Report 5002121 Amendment 1 (Appendix 8, Table 2).

All constructs of mRNA-1647 were quantifiable in most tissues analyzed, except for the kidney, where all levels were below the LLOQ. For highly exposed tissues (injection site [muscle], lymph nodes [proximal and distal], and spleen), the C_{max} was observed between 2 and 24 hours post-dose. The $T_{1/2}$ was calculated using the average tissue $T_{1/2}$ values for all 6 constructs. The results were 14.9 hours injection site (muscle), 34.8 hours for proximal (popliteal) lymph nodes, 31.1 hours for distal (axillary) lymph nodes, and 63.0 hours for spleen.

As observed with other IM delivered vaccines, the highest mRNA concentrations were observed at the injection site (muscle) followed by the proximal (popliteal) and distal (axillary) lymph nodes, consistent with distribution via the lymphatic system. These tissues, as well as spleen and eye, had tissue-to-plasma AUC ratios > 1.0.

Overall, only a relatively small fraction of the administered mRNA-1647 dose distributed to distant tissues, and the mRNA constructs did not persist past 1 to 3 days in tissues other than muscle (injection site), proximal popliteal and distal axillary lymph nodes, and spleen, in which the average $T_{1/2}$ values for all constructs ranged from 14.9 to 63.0 hours. (Table 4).

Table 4: Tissue Pharmacokinetic Parameters for a Single IM Dose of 100 µg of mRNA-1647 in Male Sprague Dawley Rats

Matrix	Construct	T_{max} (h)[a]	C_{max} (ng/mL)[a]	$AUC_{(0-t)}$ (ng × h/mL)[a,b]	$T_{1/2}$ (h)[a]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma)[c]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma) Average
Bone marrow	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.254 ± 0.0871	7.85 ± 2.03	NC	0.316	
	gL	8.0	0.224 ± 0.0920	2.78 ± 1.03	NC	0.119	
	UL128	8.0	0.292 ± 0.120	3.53 ± 1.33	NC	0.147	
	UL130	NC	NC	NC	NC	NC	
	UL131A	8.0	0.186 ± 0.0829	2.05 ± 0.912	NC	0.0825	
Brain	gB	NC	NC	NC	NC	NC	NR
	gH	24.0	0.0800 ± 0.0491	2.19 ± 1.08	NC	0.0880	
	gL	2.0	0.0360 ± 0.0360	0.144 ± 0.144	NC	0.00615	
	UL128	2.0	0.0340 ± 0.0340	0.136 ± 0.136	NC	0.00564	
	UL130	NC	NC	NC	NC	NC	
	UL131A	NC	NC	NC	NC	NC	
Distal lymph node	gB	8.0	108 ± 101	1,460 ± 1,110	31.6	64.1	62.8
	gH	8.0	110 ± 102	1,490 ± 1,130	36.2	59.8	
	gL	8.0	117 ± 109	1,460 ± 1,200	30.6	62.6	
	UL128	8.0	125 ± 117	1,620 ± 1,290	32.1	67.1	
	UL130	8.0	129 ± 121	1,630 ± 1,330	27.9	64	
	UL131A	8.0	114 ± 108	1,470 ± 1,190	28.5	59.2	

Matrix	Construct	T_{max} (h)[a]	C_{max} (ng/mL)[a]	$AUC_{(0-t)}$ (ng × h/mL)[a,b]	$T_{1/2}$ (h)[a]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma)[c]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma) Average
Eye	gB	2.0	4.72 ± 2.77	26.7 ± 13.6	NC	1.18	1.24
	gH	2.0	3.92 ± 2.19	37.6 ± 11.0	NC	1.51	
	gL	2.0	3.23 ± 1.84	29.2 ± 9.75	NC	1.25	
	UL128	2.0	3.91 ± 2.19	34.5 ± 12.2	NC	1.43	
	UL130	2.0	3.61 ± 2.14	21.3 ± 11.0	NC	0.838	
	UL131A	2.0	3.43 ± 1.96	31.1 ± 10.2	NC	1.26	
Heart	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.548 ± 0.107	9.94 ± 1.85	NC	0.400	
	gL	8.0	0.220 ± 0.0907	2.96 ± 1.05	NC	0.127	
	UL128	8.0	0.276 ± 0.113	4.49 ± 1.51	NC	0.186	
	UL130	NC	NC	NC	NC	NC	
	UL131A	8.0	0.312 ± 0.0896	3.71 ± 1.02	NC	0.150	
Injection site muscle	gB	2.0	1,770 ± 803	27,100 ± 4,880	13.5	1190	939
	gH	2.0	1,720 ± 828	26,100 ± 4,700	17.1	1050	
	gL	2.0	1,310 ± 638	20,900 ± 3,720	15.2	893	
	UL128	2.0	1,620 ± 720	25,300 ± 4,090	14.9	1050	
	UL130	2.0	1,630 ± 777	24,500 ± 4,240	13.8	961	
	UL131A	8.0	427 ± 210	12,100 ± 2,830	15.0	487	
Jejunum	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.0800 ± 0.0490	2.06 ± 1.04	NC	0.0827	
	gL	2.0	0.0700 ± 0.0429	0.720 ± 0.472	NC	0.0308	
	UL128	NC	NC	NC	NC	NC	
	UL130	NC	NC	NC	NC	NC	
	UL131A	NC	NC	NC	NC	NC	

Matrix	Construct	T_{max} (h)[a]	C_{max} (ng/mL)[a]	$AUC_{(0-t)}$ (ng × h/mL)[a,b]	$T_{1/2}$ (h)[a]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma)[c]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma) Average
Kidney	gB	NC	NC	NC	NC	NC	NR
	gH	NC	NC	NC	NC	NC	
	gL	NC	NC	NC	NC	NC	
	UL128	NC	NC	NC	NC	NC	
	UL130	NC	NC	NC	NC	NC	
	UL131A	NC	NC	NC	NC	NC	
Liver	gB	2.0	2.16 ± 1.21	8.65 ± 4.83	NC	0.381	0.499
	gH	2.0	2.12 ± 0.982	16.8 ± 4.15	NC	0.674	
	gL	2.0	1.30 ± 0.432	11.0 ± 2.37	NC	0.470	
	UL128	2.0	2.00 ± 0.814	13.7 ± 3.72	NC	0.570	
	UL130	2.0	1.87 ± 1.01	7.46 ± 4.04	NC	0.293	
	UL131A	2.0	1.99 ± 0.928	13.9 ± 4.04	NC	0.562	
Lung	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.442 ± 0.130	8.04 ± 1.96	NC	0.323	
	gL	8.0	0.274 ± 0.0984	3.45 ± 1.12	NC	0.148	
	UL128	8.0	0.340 ± 0.129	5.40 ± 1.74	NC	0.224	
	UL130	8.0	0.188 ± 0.188	2.07 ± 2.07	NC	0.0812	
	UL131A	8.0	0.310 ± 0.111	4.86 ± 1.49	NC	0.196	
Proximal lymph nodes	gB	2.0	260 ± 121	5,850 ± 949	33.5	257	201
	gH	8.0	206 ± 51.6	4,860 ± 722	38.2	195	
	gL	2.0	175 ± 81.9	3,460 ± 538	36.3	148	
	UL128	8.0	246 ± 66.6	5,190 ± 875	32.8	215	
	UL130	8.0	252 ± 67.2	5,240 ± 881	35.7	206	
	UL131A	2.0	225 ± 106	4,600 ± 719	32.2	185	

Matrix	Construct	T_{max} (h)[a]	C_{max} (ng/mL)[a]	$AUC_{(0-t)}$ (ng × h/mL)[a,b]	$T_{1/2}$ (h)[a]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma)[c]	$AUC_{(0-t)}$ Ratio (Tissue/Plasma) Average
Spleen	gB	2.0	7.36 ± 3.81	460 ± 52.9	46.9	20.2	13.4
	gH	24.0	5.63 ± 1.28	371 ± 39.5	83.0	14.9	
	gL	8.0	3.83 ± 1.04	196 ± 21.0	68.2	8.36	
	UL128	24.0	4.87 ± 1.22	297 ± 34.8	68.8	12.3	
	UL130	8.0	5.03 ± 1.41	288 ± 33.0	64.9	11.3	
	UL131A	2.0	5.10 ± 2.64	277 ± 33.1	46.2	11.2	
Stomach	gB	NC	NC	NC	NC	NC	NR
	gH	8.0	0.110 ± 0.0696	3.49 ± 1.59	NC	0.140	
	gL	8.0	0.0800 ± 0.0499	2.07 ± 1.19	NC	0.0886	
	UL128	24.0	0.102 ± 0.0648	2.85 ± 1.47	NC	0.118	
	UL130	NC	NC	NC	NC	NC	
	UL131A	24.0	0.0980 ± 0.0634	2.53 ± 1.39	NC	0.102	
Testes	gB	2.0	1.16 ± 0.719	4.64 ± 2.88	NC	0.204	0.209
	gH	2.0	1.11 ± 0.480	5.52 ± 2.20	NC	0.222	
	gL	8.0	0.420 ± 0.335	6.08 ± 3.73	NC	0.260	
	UL128	2.0	0.946 ± 0.397	4.73 ± 1.85	NC	0.196	
	UL130	2.0	0.682 ± 0.442	2.73 ± 1.77	NC	0.107	
	UL131A	2.0	0.872 ± 0.380	4.54 ± 1.85	NC	0.183	

Abbreviations: gB = glycoprotein B; gH = glycoprotein H; gL = glycoprotein L; IM = intramuscular; NC = not calculable (insufficient data points above the lower limit of quantitation); NR = not reported (some constructs measured all samples as below limit of quantitation).

[a] T_{max} and $T_{1/2}$ data reported as the mean; C_{max} and $AUC_{(0-t)}$ data reported as the mean ± standard error.

[b] For the bone marrow, brain, jejunum, heart, liver, lung, stomach, and testes, $AUC_{(0-t)}$ was calculated using less than 3 quantifiable mean concentrations and therefore is an estimate.

[c] For $AUC_{(0-t)}$ Ratio, samples listed as NC were not calculable because all samples were below limit of quantitation.

Source: Report 5002121 Amendment 1 (Appendix 8, Table 2 and Table 3)

2.6.4.5 METABOLISM

No metabolism studies with mRNA-1273 have been performed.

2.6.4.6 EXCRETION

No excretion studies with mRNA-1273 have been performed.

2.6.4.7 PHARMACOKINETIC DRUG INTERACTIONS

No PK drug interaction studies with mRNA-1273 have been performed.

2.6.4.8 OTHER PHARMACOKINETIC STUDIES

No other PK studies with mRNA-1273 have been performed.

2.6.4.9 DISCUSSION AND CONCLUSION

A non-GLP biodistribution study was completed with mRNA-1647, an mRNA-based vaccine combined in SM-102–containing LNPs, in male Sprague Dawley rats and is provided to support the development of mRNA-1273 using the Sponsor's mRNA technology platform. The biodistribution of mRNA-based vaccines in LNPs is predicted to be driven by the LNP characteristics. Therefore, mRNAs that are within an LNP of the same composition (eg, mRNA-1273 and mRNA-1647) are expected to distribute similarly.

- Concentrations for mRNA constructs were detected at levels above the LLOQ in most tissues analyzed, except for the kidney, where all levels were below the LLOQ.

- As observed with other IM-delivered vaccines, the highest mRNA concentrations were observed at the injection site followed by the proximal (popliteal) and distal (axillary) lymph nodes, consistent with distribution via the lymphatic system. These tissues, as well as spleen and eye, had tissue-to-plasma AUC ratios > 1.0.

- The T_{max} in plasma was achieved at 2 hours post-dose, with an estimated $T_{1/2}$ in plasma ranging from 2.7 to 3.8 hours. For highly exposed tissues, C_{max} was observed between 2 and 24 hours post-dose. The $T_{1/2}$ values, calculated using the average tissue $T_{1/2}$ values for all 6 constructs, were 14.9 hours for site of injection (muscle), 34.8 hours for

proximal (popliteal) lymph nodes, 31.1 hours for distal (axillary) lymph nodes, and 63.0 hours for spleen.

Overall, only a relatively small fraction of the administered mRNA-1647 dose distributed to distant tissues, and the mRNA constructs did not persist past 1 to 3 days in tissues other than muscle (injection site), proximal popliteal and distal axillary lymph nodes, and spleen, in which the average $T_{1/2}$ values for all constructs ranged from 14.9 to 63.0 hours.. The biodistribution of mRNA-based vaccines in LNPs is predicted to be driven by the LNP characteristics. Therefore, mRNAs that are within an LNP of the same composition (eg, mRNA-1273 and mRNA-1647) are expected to distribute similarly.

2.6.4.10 TABLES AND FIGURES

The tables and figures are included in the body of the document.