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2.6.3.1 PHARMACOLOGY: OVERVIEW

Study Title	Test Articles	Test System	Method of Administration	Testing Facility	Study Number (GLP Status)	Location in eCTD
Primary Pharmacodynamics						
Evaluation of Immunogenicity of a Primary Series of a Monovalent SARS-CoV-2 JN.1-containing mRNA-1273 Vaccine in Mice	PBS control mRNA-1273.815 ^a mRNA-1273.167 ^b	Mouse/ BALB/c	IM	ModernaTX, Inc. Cambridge, MA, USA	MOD-6764 (non-GLP)	4.2.1.1
Evaluation of Immunogenicity of SARS-CoV-2 JN.1-containing mRNA-1273 Vaccine Boosters in Mice	PBS control mRNA-1273.815 ^a mRNA-1273.167 ^b mRNA-1273 ^c mRNA-1273.222 ^d	Mouse/ BALB/c	IM	ModernaTX, Inc. Cambridge, MA, USA	MOD-6560 and MOD-6094 (non-GLP)	4.2.1.1

Abbreviations: eCTD=electronic common technical document; GLP=Good Laboratory Practice; IM=intramuscular; PBS=phosphate-buffered saline; S-2P=spike protein with 2 proline substitutions within the heptad repeat 1 domain; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

^a mRNA-1273.815 is a monovalent vaccine that contains a single mRNA encoding the SARS-CoV-2 S-2P antigen of the XBB.1.5/XBB.1.9.1 subvariants of Omicron. The spike protein of XBB.1.9.1 is identical to that of XBB.1.5.

^b mRNA-1273.167 is a monovalent vaccine that contains a single mRNA encoding the SARS-CoV-2 S-2P antigen of the JN.1 subvariant of Omicron.

^c mRNA-1273 is a monovalent vaccine that contains a single mRNA encoding the spike protein of the Wuhan-Hu-1 isolate of SARS-CoV-2.

^d mRNA-1273.222 is a bivalent vaccine that is a coformulation of mRNA-1273 (ancestral) and mRNA-1273.045 (contains a single mRNA encoding the SARS-CoV-2 S-2P antigen of the BA.4/BA.5 subvariants of Omicron).

2.6.3.2 PRIMARY PHARMACODYNAMICS

Primary pharmacodynamics studies are summarized in the Pharmacology Written Summary ([Section 2.6.2](#)).

2.6.3.3 SECONDARY PHARMACODYNAMICS

No secondary pharmacodynamic studies have been performed with a JN.1-containing vaccine.

2.6.3.4 SAFETY PHARMACOLOGY

No safety pharmacology studies have been performed with a JN.1-containing vaccine.

2.6.3.5 PHARMACODYNAMIC DRUG INTERACTIONS

No pharmacodynamic drug interaction studies have been performed with a JN.1-containing vaccine.