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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 SARS-CoV-2 LP.8.1-containing mRNA-1273 vaccine in mice	PBS control mRNA-1273.712 ^a mRNA-1273.167 ^b mRNA-1273.251 ^c	Mouse/ BALB/c	IM	ModernaTX, Inc. Cambridge, MA, USA	(non-GLP)	
Evaluation of immunogenicity of a monovalent SARS-CoV-2 LP.8.1-containing mRNA-1273 vaccine booster in mice	PBS control mRNA-1273.712 ^a mRNA-1273.167 ^b mRNA-1273.251 ^c mRNA-1273 ^d mRNA-1273.045 ^e mRNA-1273.815 ^f	Mouse/ BALB/c	IM	ModernaTX, Inc. Cambridge, MA, USA	(non-GLP)	

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

^a mRNA-1273.712 vaccine contains a single mRNA encoding the SARS-CoV-2 S-2P antigen of KP.2 subvariant of JN.1.

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

^c mRNA-1273.251 vaccine contains a single mRNA encoding the SARS-CoV-2 S-2P antigen of the LP.8.1 subvariant of JN.1.

^d mRNA-1273 vaccine contains a single mRNA encoding the SARS-CoV-2 S-2P antigen of the Wuhan-Hu-1 (original) strain.

^e mRNA-1273.045 is a single mRNA encoding the SARS-CoV-2 S-2P antigen of the BA.4/BA.5 subvariants of Omicron. In this study, mice receive bivalent vaccine containing 1:1 benchside mix of separately formulated mRNA-1273.045 and mRNA-1273 (original).

^f mRNA-1273.815 vaccine contains a single mRNA encoding the SARS-CoV-2 S-2P antigen of the XBB.1.5 subvariant of Omicron.

2.6.3.2 PRIMARY PHARMACODYNAMICS

Primary pharmacodynamics studies are summarized in the Pharmacology Written Summary (Section 2).

2.6.3.3 SECONDARY PHARMACODYNAMICS

No secondary pharmacodynamic studies have been performed with a LP.8.1-containing vaccine.

2.6.3.4 SAFETY PHARMACOLOGY

No safety pharmacology studies have been performed with a LP.8.1-containing vaccine.

2.6.3.5 PHARMACODYNAMIC DRUG INTERACTIONS

No pharmacodynamic drug interaction studies have been performed with a LP.8.1-containing vaccine.

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