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2.6.3.1 PHARMACOLOGY: OVERVIEW

Test Article: mRNA-1273

Type of Study	Test System	Method of Administration	Testing Facility	Report Number	Location in eCTD
Primary Pharmacodynamics					
Evaluation of in vitro expression of SARS-CoV-2 mRNA and in vivo expression of mRNA-1273	HEK293T cells[a]	In vitro transfection	ModernaTX, Inc. Cambridge, MA USA	MOD-4112.1273	4.2.1.1
	BALB/c mice	IM			
Evaluation of immunogenicity, protective capacity, and safety in young mice	Mouse (young), BALB/cJ, C57BL/6J and B6C3F1/J	IM	Viral Pathogenesis Laboratory, Vaccine Research Center, National Institutes of Health Building 40 Room 2608 Bethesda, MD 20892 (b) (4)	VRC01	4.2.1.1
Immunization and protein restimulation in young BALB/c mice with enhanced respiratory disease endpoint monitoring	Mouse (young), BALB/c	IM	ModernaTX, Inc. 200 Technology Square Cambridge, MA 02139	MOD-3937	4.2.1.1
Immunogenicity and determination of titer dynamic range in young BALB/c mice	Mouse (young), BALB/c	IM	ModernaTX, Inc. 200 Technology Square Cambridge, MA 02139	MOD-3938/3940	4.2.1.1

Type of Study	Test System	Method of Administration	Testing Facility	Report Number	Location in eCTD
Immunogenicity and characterization of cellular response in young BALB/cJ mice	Mouse (young), BALB/cJ	IM	Viral Pathogenesis Laboratory Vaccine Research Center National Institutes of Health Building 40, Room 2608 Bethesda, MD 20892 (b) (4)	VRC05	4.2.1.1
Efficacy and enhanced respiratory disease in aged BALB/c mice	Mouse (aged), BALB/c	IM	Viral Pathogenesis Laboratory, Vaccine Research Center, National Institutes of Health Building 40, Room 2608 (b) (4)	VRC02	4.2.1.1
Five-week (2 doses: prime/boost) repeat dose immunogenicity with safety endpoints	Rat, Sprague Dawley	IM	Charles River Laboratories, Inc. 54943 North Main Street Mattawan, MI 49071	2308-123	4.2.3.7.7
Protection from WT SARS-CoV-2 in hamsters using optimal and suboptimal doses	Hamster, golden Syrian	IM	University of Texas Medical Branch 301 University Blvd Galveston, TX 77555	UTMB01	4.2.1.1

Type of Study	Test System	Method of Administration	Testing Facility	Report Number	Location in eCTD
Immunogenicity and protective efficacy in NHPs	NHP, rhesus macaque (Indian-origin)	IM	Viral Pathogenesis Laboratory, Vaccine Research Center, National Institutes of Health Building 40 Room 2608 (b) (4)	VRC04	4.2.1.1
Evaluation of immunogenicity and efficacy from expanded dose range in NHPs	NHP, rhesus macaque (Indian-origin)	IM	Viral Pathogenesis Laboratory, Vaccine Research Center, National Institutes of Health Building 40 Room 2608 Bethesda, MD 20892 Vaccine Immunology Program 9 West Watkins Mill Road Gaithersburg, MD 20878 (b) (4)	VRC07	4.2.1.1

Abbreviations: eCTD = electronic common technical document; GLP = Good Laboratory Practice; IM = intramuscular; mRNA = messenger RNA; NHP = nonhuman primate; SARS-CoV-2 = 2019 novel coronavirus; WT = wild type.

[a] For the in vitro portion of the study, the test article was an mRNA construct that encodes the SARS-CoV-2 spike protein modified with 2 proline substitutions within the heptad repeat 1 domain.