

Table of Contents

Table of Contents	1
2.6.3.1 Pharmacology: Overview	2

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 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 Baric Laboratory University of North Carolina at Chapel Hill Michael Hooker Research Building Chapel Hill, NC 27599 Denison Laboratory Vanderbilt University Medical Center Nashville, TN 37232	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

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 Baric Laboratory University of North Carolina at Chapel Hill Michael Hooker Research Building Chapel Hill, NC 27599	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 Bethesda, MD 20892 Baric Laboratory University of North Carolina at Chapel Hill Michael Hooker Research Building Chapel Hill, NC 27599	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

Immunogenicity and protective efficacy in NHPs	NHP, rhesus macaque (Indian-origin)	IM	<p>Viral Pathogenesis Laboratory, Vaccine Research Center, National Institutes of Health Building 40 Room 2608 Bethesda, MD 20892</p> <p>Bioqual, Inc. 9600 Medical Center Drive Suite 101 Rockville, MD 20850-3336</p> <p>University of North Carolina School of Medicine 125 Mason Farm Road Chapel Hill, NC 27599</p>	VRC04	4.2.1.1
Evaluation of immunogenicity and efficacy from expanded dose range in NHPs	NHP, rhesus macaque (Indian-origin)	IM	<p>Viral Pathogenesis Laboratory, Vaccine Research Center, National Institutes of Health Building 40 Room 2608 Bethesda, MD 20892</p> <p>Vaccine Immunology Program 9 West Watkins Mill Road Gaithersburg, MD 20878</p> <p>Bioqual, Inc. 9600 Medical Center Drive Suite 101 Rockville, MD 20850-3336</p> <p>University of North Carolina School of Medicine 125 Mason Farm Road Chapel Hill, NC 27599</p>	VRC07	4.2.1.1

Abbreviations: eCTD = electronic common technical document; GLP = Good Laboratory Practice; IM = intramuscular; NHP = nonhuman primate; WT = wild type.