

2.6.3.1 Pharmacology: Overview

Test Article: COMIRNATY® (COVID-19 Vaccine, mRNA)

Type of Study	Test System	Method of Administration	Testing Facility	Study Number
Primary Pharmacodynamics				
In Vitro Expression of BNT162b2 Drug Substance and Drug Product	In vitro cell culture	NA	BioNTech (Mainz, Germany)	R-20-0211
Qualification of the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay	In vitro cell culture	NA	University of Texas Medical Branch (Galveston, TX)	VR-MQR-10214
Structural and Biophysical Characterization of SARS-CoV-2 Spike Glycoprotein (P2 S) as a Vaccine Antigen	In vitro cell culture	NA	Pfizer (Groton, CT)	VR-VTR-10741
Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Sera	Direct Luminex immunoassay	NA	Pfizer (Pearl River, NY)	VR-MQR-10211
COVID-19: Immunogenicity Study Of The LNP-Formulated ModRNA Encoding The Viral S Protein-V9	BALB/c mice	IM	BioNTech (Mainz, Germany)	R-20-0085
Characterizing the Immunophenotype In Spleen And Lymph Node Of Mice Treated With SARS-CoV-2 Vaccine Candidates	BALB/c mice	IM	BioNTech (Mainz, Germany)	R-20-0112
Evaluation of COVID-19 Variant-Modified Vaccines in Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-10944
Immunogenicity of Monovalent and Bivalent BA.4/BA.5 Variant-Modified Vaccines in Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-10976
Immunogenicity of Monovalent and Bivalent XBB.1.5 Variant-Modified Vaccines in Naive Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11122
Immunogenicity of COVID-19 Monovalent and Bivalent XBB.1.5 Sublineage-Modified Vaccines in BNT162b2 Experienced Mice as a Fourth Dose Booster	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11123

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Immunogenicity Evaluation of BNT162b2 JN.1 as a Primary Series in Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11311
Immunogenicity Evaluation of BNT162b2 JN.1 as a Fifth Vaccination in Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11313
Immunogenicity Evaluation of KP.2 and JN.1-Adapted BNT162b2 as a Primary Series in Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11341
Immunogenicity Evaluation of KP.2 and JN.1-Adapted BNT162b2 as a Fourth Vaccination in Vaccine-Experienced Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11342
Immunogenicity Evaluation of XEC- and LP.8.1-Adapted BNT162b2 in Naïve Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11467
Immunogenicity Evaluation of XEC- and LP.8.1-Adapted BNT162b2 in Vaccine-Experienced Mice	BALB/c mice	IM	Pfizer (Pearl River, NY)	VR-VTR-11466
BNT162b2 (V9) Immunogenicity and Evaluation of Protection against SARS-CoV-2 Challenge in Rhesus Macaques	Rhesus macaques	IM	Pfizer (Pearl River, NY) New Iberia Research Center (New Iberia, LA) SNPRC (San Antonio, TX)	VR-VTR-10671

Secondary Pharmacodynamics

Studies not conducted

Safety Pharmacology

Studies not conducted

Pharmacodynamic Drug Interactions

Studies not conducted

COVID-19 – Coronavirus disease 2019; dLIA – Direct Luminex Assay; IgG – immunoglobulin G; IM - intramuscular; NA – not applicable;
SARS-CoV-2 – severe acute respiratory syndrome coronavirus 2; SNPRC – Southwest National Primate Research Center.