

COVID Vaccines US

Immunogenicity and Safety Information Reviewed by Work Group

mRNA1273 (Moderna) N=130

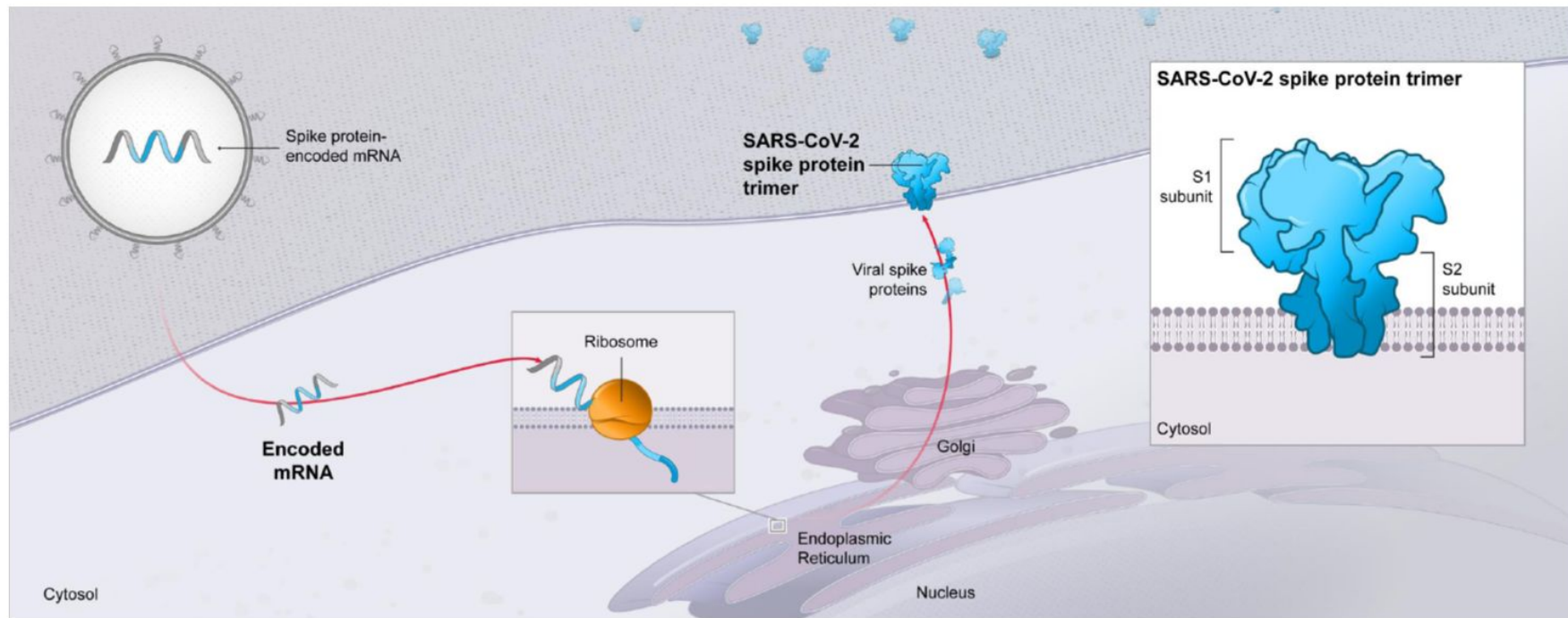
■ Immunogenicity

- Neutralizing antibodies (pseudovirus neutralization assay titers) and binding antibodies (ELISA) measured 7 days post-dose 2
- Responses similar to or exceeded convalescent sera comparison
- Th1-biased CD4+ T-cell response
- **100µg** dose selected for Phase III clinical trials

■ Safety

- Local and systemic symptoms followed for 7 days post-vaccination
 - Pain, myalgia, fatigue most common symptoms reported
- Reactogenicity symptoms higher after second dose
- No vaccine-related serious adverse events (SAEs) reported

mRNA-1273 encodes for the full-length Spike Protein in the Pre-fusion Conformation (S-2P)



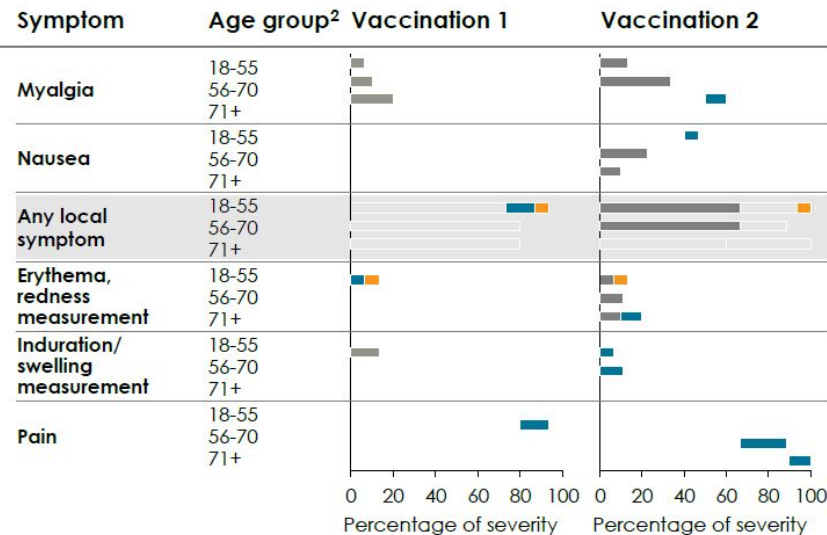
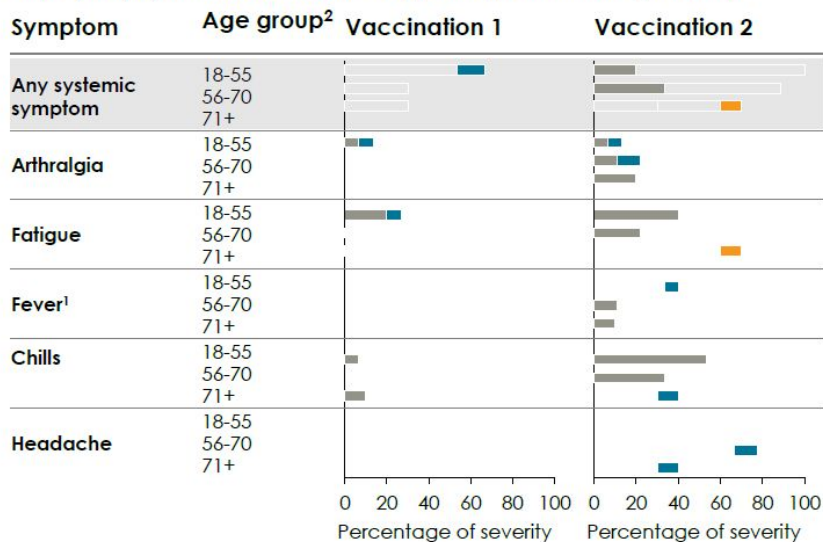
100 mcg mRNA-1273 Well-Tolerated Across Age Groups

Phase 1: No Vaccine-Related SAEs Have Been Reported

Solicited Local and Systemic Symptoms Followed for 7 Days Post-vaccination

Majority of symptoms resolved within 2 days, some persisted as long as 5 days

■ Grade 1 (mild) ■ Grade 2 (moderate) ■ Grade 3 (severe)



1. Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment
2. 18-55: N=15; 56-70: N=10; 71+: N=10; N = All subjects receiving Dose 1 with any solicited event data recorded in the database

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BNT162b2 (Pfizer/BioNTech)

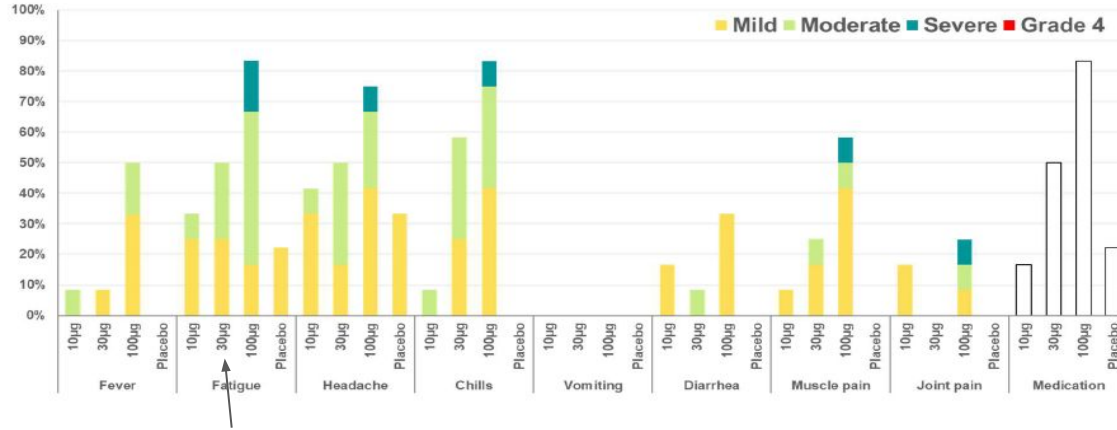
N=195

■ Immunogenicity

- Neutralizing antibodies (50% neutralization titers) measured 7 days post-dose 2
- Responses similar to or exceeded human convalescent panel
- CD4+ and CD8+ T cell response demonstrated
- Th1-biased CD4+ T-cell response
- **30µg** dose of BNT162b2 selected for Phase III clinical trials

■ Safety

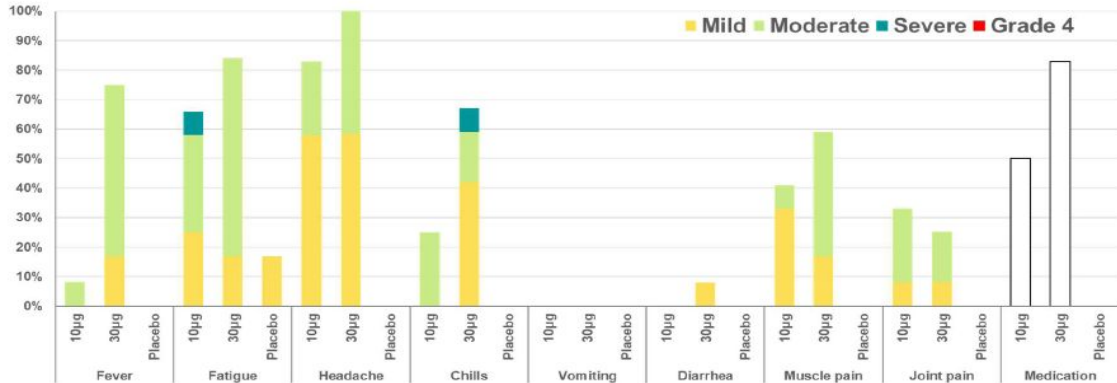
- Local and systemic symptoms followed after administration
 - Fatigue, headache and muscle pain most common
- Reactogenicity symptoms lower in older population (65-85 years)

a

30 is the ongoing dose for Phase 3.

Top is dose 1

Bottom is dose 2

b

Work Group Interpretation

- Phase I data from both mRNA vaccines show induction of neutralizing antibodies at 7 days post-dose 2 that exceed levels in convalescent sera
- Data from both mRNA vaccines support advancing to large scale Phase III clinical trials to assess safety and efficacy
- Diverse cold-chain or ultra-low temperature requirements can substantially affect implementation efforts

Awaiting phase 3 Full data

- Looking at symptomatic disease of covid in those that are vaccinated as the primary endpoint.
- Implementation plans for Front line targeted at Nov 1 pending the ACIP clearance
- Pfizer 2 doses, day 0, 21- Needs ultra cold chain
- Moderna 2 doses, day 0, 28, needs regular cold chain.
- Utah will have 500,000 doses before end of 2020
- Allocation and prioritization of vaccine will go to highest risk occupations/persons first