Guardian Consulting Services, Inc.

Consultant Pharmacists for Healthcare Organizations, Industry, and the Community.

COVID-19 Vaccine Candidates in Phase 3 Trials (USA)

Last updated 10/17/2020

Sponsor	Vaccine Type	# Doses needed	Storage Requirements/Stability	Notes *("Purchase" dependent on FDA approval)*
Moderna ***mRNA-1273*** 30,000 volunteers in 89 US sites (Phase 3 Start: July 27)	mRNA	Two doses 0, 28 days	Deep Freeze: -20C (-4F); 7 days in refrig after thawing	US: 100 million doses purchased, option to buy an additional 400 million doses No mRNA vaccines currently on market for any use Advantage: fast development
BioNTech/Pfizer/Fosun Pharma ***BNT162b2*** 30,000 volunteers in US, Brazil, Argentina, Germany (Phase 3 Start: July 27)	mRNA	Two doses 0, 28 days	Deep Freeze: -70C(-94F); 24 hours after thaw, 2 hours at room temp	US: 100 million doses purchased, option to buy an additional 400 million doses No mRNA vaccines currently on market for any use Advantage: fast development **Per Mfr: Likely to apply for EUA by late Nov 2020**
AstraZeneca/Oxford University ***AZD1222*** Trials underway in England, India, Brazil, S Africa, USA (Phase 3 Start Aug 31)	Modified Adenovirus	Single dose	*"expected to require refrigeration"*	US: 300 million doses purchased 1 serious ADR reported: Transverse Myelitis, trial briefly halted then restarted in September. **(Trial currently on HOLD in USA)**
Janssen ***JNJ78436735 (formerly Ad26.COV2-S)*** 60,000 volunteers/3 continents (Phase 3 Start Sept 21)	Modified Adenovirus	Single Dose	*"can be stored in refrigerator at least 3 months"*	US: 100 million doses purchased, option to buy an additional 200 million doses **(Trial currently on HOLD in USA)**

6/30/2020: FDA Industry COVID-19 Vaccine Development Guidance released: https://www.fda.gov/media/139638/download

***Per above, Study Endpoints:* "…prevent disease or decrease its severity in at least 50% of people who are vaccinated"**

9/23/2020: The FDA proposed additional guidance that would require vaccine candidates to have **at least 2 months follow up tracking** after final dose before an emergency use authorization EUA would be considered.