*2 February 2021*

# ***BRIEF19***

*A daily review of covid-19 research and policy*

## ***RESEARCH BRIEFING***

**Johnson & Johnson Janssen covid-19 vaccine 85 percent effective by Day 28 and 100 percent effective by Day 49.**

Last week, headlines and stories circulated about the Johnson & Johnson (J&J)/Janssen vaccine based on a press release containing data from an interim analysis of their phase 3 clinical trial. The data made public at that time indicate that another weapon against SARS-CoV-2 could soon become available in the United States. This would be particularly helpful because in the effort to vaccinate more people, as the J&J vaccine does not require a second booster a.

The data released come from the ongoing ENSEMBLE Trial, a randomized, double-blind, placebo-controlled phase 3 study (i.e. meaning that thousands of patients are being enrolled) that assesses the safety and efficacy of vaccine. Unlike the Pfizer/BioNtech and Moderna vaccines, which rely on mRNA technology, the J&J vaccine is a so-called recombinant vector, meaning it uses a modified human adenovirus as a delivery mechanism for the genetic code for the spike protein of SARS-CoV-2.

Importantly, the J&J vaccine is a *single dose* vaccine as compared to the two currently authorized mRNA vaccines, which require 2 doses of the vaccine three to four weeks apart. Additionally, J&J reports that the "single-dose vaccine candidate is estimated to remain stable for two years at -20°C (-4°F), at least three months of which can be at temperatures of 2-8°C (36°F–46°F)," meaning that unlike the current options, refrigeration will suffice for the last few legs of the journey that any particular lot of the vaccine makes,

The results are impressive. The ENSEMBLE trial enrolled over 43,000 participants ages 18 years and older across three geographic regions, the United States, Latin America, and South Africa. Approximately 1 percent of patients enrolled in the study developed covid-19. The J&J single dose vaccine was 66 percent effective at preventing moderate *and* severe Covid-19 by day 28 after vaccination among all participants from the above-mentioned regions, including those regions with an emerging viral variant. Protection against SARS-CoV-2 was greatest in the United States (72 percent) and worst in South Africa (57 percent) where potentially more infectious variants have been reported recently. These results are likely to be further confounded by participant exposure to emerging viral variants; nearly 95 percent of all participants who developed covid-19 in South Africa were found to have been infected with SARS-CoV-2 from the B.1.351 lineage. That particular lineage has been found to resist at least to some degree antibodies generated by previous infections and other vaccines, as covered in *Brief19*.

However, with respect to the prevention of *severe* disease, the J&J vaccine was 85 percent effective across all regions by post-vaccination day 28. But most interestingly, J&J announced that there were *no cases* of severe covid-19 among participants after post-vaccination day 49. Does this mean the J&J vaccine is 100 percent effective at preventing severe covid-19 by day 49? We will only know that once the full data are released—but it is possible, based on these preliminary reports. In addition, no participants who received the J&J vaccine were either hospitalized for covid-19 nor died 28 days post-vaccination. This implies that one shot and one month of waiting could eliminate the most feared complications of SARS-CoV-2 infection, assuming that new variants do not render these findings obsolete.

Serious adverse events (i.e. side effects) were reportedly rare, with more participants in the placebo group reporting adverse events compared to those who received J&J vaccine. This implies that some of the adverse events reported by patients in the placebo arm may in fact be

related to subsequently developing covid-19 itself, rather than as a result of anything in the vaccine or placebo shots themselves. The rates of fever were 9 precent, with Grade 3 fevers (greater than 39°C or 102.1°F) occurring just 0.2 percent of the time.

In light of this release, J&J announced it will file for Emergency Use Authorization in the United States in early February with plans to have the vaccine immediately available to ship when authorization is provided. Although these results were announced by press release, so far results from the large vaccine trials have had such impressive results, that even "science by press release" have ended up being borne out by the actual data when subsequently released. We hope the same is true for this vaccine. *—Joshua Niforatos, MD, MTS*

## ***POLICY BRIEFING***

**President Biden meets with Senate Republicans proposing smaller coronavirus relief package.**

President Biden met on Monday with a coalition of ten Republicans pitching a coronavirus relief package that is much than his $1.9 trillion plan that has been embraced by the Democratic majority. The counter proposal offered by the GOP lawmakers currently carries a $618 billion price tag. This alternative plan has yet to receive the support of any Democrats.

The question remains as to whether President Biden will forge ahead with his original plan without GOP support, or whether he will call for a scaling down of the coronavirus relief package in effort to ensure bipartisan policymaking. The Republican compromise plan would, among other things, send smaller direct payment to individuals ($1000 instead of $1400), extend $300 per week federal unemployment benefits, but only through June 30, and retain the $160 billion of the Biden package aimed at increasing vaccinations and controlling the spread of coronavirus. A difference is that the Republican counterproposal would not include any support for state and local governments, a core Democratic priority. Ahead of the meeting, the White House reaffirmed its support for the $1.9 trillion package, saying that "the risk is that it is too small," a remark that does not bode well for the Republicans seeking to scale back what they view as too costly a government intervention. Biden's top economic adviser Brian Deese said that the White House is reviewing the Republicans' letter addressing the relief package and expressed willingness to discuss how to make the relief package more effective, though he declined to say whether the $1.9 trillion in spending is negotiable. Senate Majority Leader Chuck Schumer and Senate Finance Committee Chairman Ron Wyden dismissed the Republican plan as inadequate, with Schumer likewise warning that failure to spend now would cause more pain moving forward. That ten Republicans signed on to this compromise stimulus plan is noteworthy because, were the proposal to gain complete Democrat support, it would bring the number of votes to 60, filibuster-proof under current Senate rules.

With the counteroffer being less than a third of the financial commitment under the Democrats' proposed relief package, the question remains whether the Biden meeting with these ten Republicans represents a meaningful negotiation given a desire for a filibuster-proof coalition, or whether the meeting and any others that may follow are simply polite exchanges that will precede the Democrats moving forward with their preferred coronavirus relief package. Biden may remember that during the negotiations over President Obama's Affordable Care Act, several Republicans indicated a willingness to negotiate, but ultimately said "no," to every proposed idea, leading to a vote that went down party lines. *—Miranda Yaver, PhD*

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