NEUBERGER BERMAN

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COVID-19 Update: News on Vaccines, Views from Dr. Gottlieb

Vaccine Developments

This past weekend brought various news tied to COVID-19 vaccine trials, including Oxford University/AstraZeneca vaccine trial restarts, Moderna updates to enrollment, Pfizer expanding enrollment to include a broader population and Merck trials getting going.

- Moderna updated enrollment in its Phase 3 study late Friday night with 23,497 participants having now enrolled, or an increase of 2,086 over the prior week compared to enrollment increases of 3,953 and 4,264 in the previous two weeks. The company stated that ~27% of enrollees are from diverse communities.
- Pfizer expanded enrollment in its Phase 3 COVID-19 study to include younger patients (16 – 18 yrs.) as well as older patients, suggesting to us that safety to date looks unremarkable.
- Merck initiated its Phase 1/2 trials with COVID-19 vaccine candidate V591, dosing volunteers in Belgium, according to an article in *The Wall Street Journal*. Recall that Merck had been criticized for being "late to the party," but we tend to agree with CEO Kenneth Frazier that careful selection of the right platform could prove advantageous in the long run and view their attenuated measles vector system as affording broader responses from both antibodies and T cells.

Scott Gottlieb's Take on COVID-19

Dr. Gottlieb, the former Food and Drug Administration commissioner, has been making the rounds on the virus and COVID-19. In a recent opinion piece, he reiterated his views on a staged rollout of the vaccine, saying he still believes Pfizer-BioNTech will have data in mid-October despite increasing/broadening enrollment in their vaccine trial. Regarding the Trump administration's influence on vaccine approval and launch, he pushed back on conspiracy theories and doesn't see an emergency use authorization (EUA) before the November 3 election in either case, given tight timelines. Dr. Gottlieb also thinks that the October 22 FDA advisory meeting will focus on guidelines more than anything else. Below are key comments from Dr. Gottlieb that we found incremental from a timeline and approval-hurdle perspective:

- Safety concerns regarding the Oxford University/Astra Zeneca vaccine are rational given adenoviral vectors and their association with inflammatory/neurological reactions such as Guillain Barre and transverse myelitis; he believes they are more likely due to the platform rather than the antigen (Spike protein).
- A EUA guidance document is coming out in a few weeks and should opine on the number of patients, with at least 6-8 weeks of follow-up safety data required in order for an EUA to be granted.
- Dr. Gottlieb is leaning towards SARS-CoV2 (the virus that causes COVID-19) becoming seasonal, with higher spread this fall and winter, a decline in spring 2021 but a resurgence in fall 2021. However, he projects that at least 20% of the U.S. population will have been infected by fall 2021 outside of vaccination, so the spread may be a bit slower when coupled with mask wearing and social distancing.
- On efficacy, antibodies are key in his view. T cells will help in responding to second infections should they occur, but he cautioned that they will not protect from infection but just diminish the severity of COVID-19. He thinks sterilizing immunity from vaccines will not occur, so he is bullish on the outlook for recombinant antibody therapeutics. To this end, he expects initial viral load data by the end of September and, if positive, thinks the vast safety database on recombinant antibodies could give FDA comfort on early approval if need be, and he is in agreement with our house view that odds are better for utility in early disease and prophylaxis vs. treatment setting.
- Finally, on what is evolving as a COVID-19 syndrome, Dr. Gottlieb is disappointed regarding the availability of other clinical sequelae data from the CDC database (or lack thereof), views reported cardiac adverse events as perhaps initially misdiagnosed for pulmonary issues (i.e. emboli vs. pneumonia) and thinks more aggressive treatment of clotting disorders to will help decrease mortality going forward.

Where Do We Stand on the Pandemic?

With the number of new daily cases in the U.S. stubbornly stable at around 38,000 – 40,000 per day, despite back-to-school spikes and a gradual return to a new "normal," we think that daily tracking will be less important going forward.

We view the hospitalization data as encouraging, demonstrating lessons learned from months ago on how to better treat COVID-19 patients (we think steroids and anticoagulants have had the most impact) as well as a case fatality rate of ~3% as reasons for some optimism as we await recombinant antibody biomarker data expected by the end of September and initial vaccine data in mid- to late October.

While SARS-CoV2 will likely remain in circulation for the next few years, reinfection data coupled with our view that T-cell responses triggered by vaccination could lessen the severity of COVID-19 all contribute to our growing confidence that this virus may eventually become more of a nuisance virus, similar to the other four coronaviruses that cause a bad cold. We are carefully monitoring the current second waves in Spain, France and the U.K. for evidence of a less severe course of COVID-19, which could add to our view of memory responses from natural infection, which should likely be more pronounced post-vaccination.