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COVID -19 Update: Optimism Growing for the US COVID-19 Outlook

The U.S. is stabilizing; testing is not as bad as media portrays; science is closing in on recombinant antibody and vaccine data; and emerging data that memory T-cell responses to SARS-CoV2 (the virus that causes the COVID-19 disease) are providing more durable immunity, all support our view as we approach what may be the beginning of the end of COVID-19.

It has been a bit over a month since our last COVID-19 update by design, as we thought more data points were needed before we could paint an accurate picture of the pandemic in the U.S. While clusters of outbreaks are something we all may need to accept as part of our lives until vaccines are broadly available in first half of 2021, we think Americans are finally grasping the benefits of masks, social distancing and the time it will take to return society to a new normal, one that possibly is an improved version of pre-COVID-19 lifestyles.

Where are we in the pandemic?

Only six states are setting single-day records in new cases, the virus reproductive rate is holding steady under 1.0 (at 0.96) and doubling time remains at ~70 days, a number we expect to rise over the next month (higher is better)—all suggesting a slowing outbreak. With school reopenings and flu season right around the corner, we expect "fluvid" diagnostic tests and better surveillance programs to help mitigate the outbreak—though approvals of such tests remain elusive to date and we appear to be still more than a month away from recombinant antibody data and two months from vaccine data, both needed to help determine the country's direction in the near term. Still, the U.S. mortality rate is holding steady around 3%, current hospitalizations appear under control post the late-July spike (except for Wisconsin, which we are carefully monitoring), and the 7-day average daily new-case count hovers around ~52,000, with recent data in the 40,000s.















Testing update: *Testing is reported to be at 775,000 to 800,000 tests per day. Ideally we would like it to be closer to 900,000 to 1,000,000 per day. New saliva tests could get us there.* The seven-day average of 782,000 tests per day has dipped below the 806,716 tests conducted a few days ago, which was the daily peak. Testing service provider Quest voiced a need for more instruments to meet demand and improve turnaround times; producers/suppliers such as Thermo Fisher Scientific, Roche and Danaher report robust supply sales of reagents, instruments and PPE, and limited if any shortages. Importantly, the U.S. has now conducted over 66M tests with a 7-day average positivity rate of 6.9%.



Source: The COVID Tracking Project as of 8/17/2020.

The chart above supports that the number of states and territories meeting World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) guidelines for reopening (a positivity rate of 5% or below for 14 consecutive days). Most states at the far left are in the Northeast, but also include Oregon, Michigan, New Mexico, Colorado and Illinois, previous "hotspots." Interestingly, the data supports that five states are slightly above the 5% bogey on positivity rates, including Pennsylvania, Rhode Island and Louisiana. Nothing surprising to us with regard to Texas, Florida, Georgia and Arizona clustering to the right, indicative of ongoing outbreaks. PR and WA have low denominators and are experiencing modest clusters.

Food and Drug Administration (FDA) grants emergency use authorization (EUA) for a second saliva-based coronavirus test according to the Hill.com.

Saliva Direct was developed by Yale University and validated through testing of NBA players and staff who are asymptomatic or at high risk. Recall that back in mid-April the FDA granted EUA to an at-home saliva collection approach developed at Rutgers University and in partnership with Spectrum DNA and Accurate Diagnostics Labs, but at a cost of \$150 per kit, it hasn't really taken off. The Yale test reports to be an "open source" test; with its partner Jackson Laboratory for Genomic Medicine, it is seeking ways to make this test more broadly available at reasonable prices, with some proposing ~\$10 per test. We believe success in creating an accurate at-home test for this price would not only help increase daily testing volume in the U.S. but also limit virus spread.

Updates on vaccines and immunity: Both antibodies and T-cell responses are needed, but the emerging data on the latter suggests protection could last longer than the CDC's most recent statement of roughly three months.

Regarding vaccine development, sixteen COVID-19 vaccines have entered clinical trials, though we view six of them as most viable (hence our focus). Moderna and Pfizer/BioNTech are in or about to enter phase III trials, with Oxford University/AstraZeneca close behind. Johnson & Johnson and Novavax are about to begin phase II/III, while Sanofi and GlaxoSmithKline are expected to initiate trials shortly. Additionally, Pfizer, Moderna, AstraZeneca and Novavax all reported to have demonstrated robust neutralizing antibody data. T cell data is thin, but most showed a CD4+ response, vital for long-term immunity. We anticipate initial clinical data from the Pfizer/BioNTech program in late September/early October, with AstraZeneca and Moderna data shortly thereafter based on pacing of enrollment.

NEUBERGER BERMAN August 2020

An article to be published in the journal *Cell* reported that a 200-patient study in Sweden that demonstrated that SARS-CoV2 memory T cells were detectable in antibody-negative, COVID-19 exposed family members and recovered patients with a history of mild COVID-19 and asymptomatic COVID-19. Additionally, a study to appear in the journal *Nature* shows similar effects, and suggests that individuals could be protected against recurrent episodes of infection for at least a year or more, especially if SARS-CoV2 -specific memory cells are similar to those of SARS-CoV1 (SARS epidemic of 2003 in China and Toronto). Should such memory responses prove true and are broadly reported, fears over waning antibody responses to various SARS-CoV2 vaccines should likely dissipate, possibly bringing T-cell responses more into focus, providing a substantial opportunity for Adaptive Biotechnology's T-cell mapping segment.

With all this focus on vaccines, could the uptake be as broad as the market thinks?

We have stated in the past that decisions on whether or not to be first in line for a SARS-CoV2 vaccine will likely hinge on efficacy data, comorbid conditions/age, as well as status of the outbreak in specific areas upon first emergency use authorization later this Fall. The survey below was conducted over the last two weeks of July.



Source: RobertPearlMD.com, Forbes as of 8/10/2020

Updated poll conducted by RobertPearIMD.com the last two weeks of July and represents opinions of a total of 461 individuals. 55% of those polled were healthcare professionals. The data supports that 23% of Americans and 54% of healthcare professionals will voluntarily take the vaccine upon emergency approval, with 53% of Americans willing to take the vaccine upon "further safety testing" and 4% "will not voluntarily opt in."

Lastly, with the Administration and Department of Health and Human Services' (HHS) recent announcement regarding employing the expertise of the private sector for assistance in vaccine distribution, namely McKesson, we think Americans will be able to obtain a vaccine from either their physician, local clinic or possibly at their pharmacy in states that allow administration of vaccines by a pharmacist.

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For more information on COVID-19, please refer to the Center for Disease Control and Prevention at cdc.gov.

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