



# COVID-19 Scientific and Public Health Policy Update<sup>1</sup> – (20 October 2020)

In addition to our Weekly Outbreak Brief on the spread of COVID-19 and the actions that Africa CDC is taking to help African Union Member States. Africa CDC shares a weekly brief detailing the latest developments in scientific knowledge and public health policy from around the world, as well as updates to the latest guidance from WHO and other public health agencies. Contents of this document are <u>not intended to serve as recommendations</u> from the Africa CDC; rather, it is a summary of the scientific information available in the public space to Member States. It is important to note that the outbreak is evolving rapidly and that the nature of this information will continue to change. We will provide regular updates to ensure Member States are informed of the most critical developments in these areas.

### A. Executive summary

- Phylogenetic analysis of SARS-CoV-2 genomes from samples collected during the early phase of the pandemic in Kenya identified 8 global lineages and at least 76 independent SARS-CoV-2 introductions into the Kenyan coast. The dominant B.1 lineage (European origin) accounted for 82.1% of the cases.
- A cross-sectional study reports on the sero-prevalence of SARS-CoV-2 in Addis Ababa. The SARS-CoV-2 sero-prevalence was estimated at 8.8% for the study population with a higher sero-prevalence observed for males (9.0%) suggesting that more individuals had been infected in Addis Ababa than what was being detected and reported by RT-PCR test suggestive of community transmission.
- The WHO SOLIDARITY and RECOVERY trial report on whether various regimes (lopinavir–ritonavir – for RECOVERY; Remdesivir, Hydroxychloroquine, Lopinavir and Interferon regimens – for SOLIDARITY) under investigation had an effect on outcomes in patients admitted to hospital with COVID-19. Findings indicate no effects on overall mortality, ventilation and duration of hospital stay for COVID-19 patients.
- A dynamic COVID-19 microsimulation model was developed to evaluate clinical and economic outcomes and cost-effectiveness of epidemic control strategies in KwaZulu-Natal, South Africa. Findings indicate that strategies involving contact tracing, isolation centres, mass symptom screening, and quarantine centres for contacts who test negative would substantially reduce COVID-19 mortality and be cost-effective.

<sup>&</sup>lt;sup>1</sup> This update compiled for use by Africa CDC and African Union Member States and is developed in collaboration with the World Health Organization - Regional Office for Africa. **This is a preliminary summary of information and not considered policy, guidance, or final conclusions of the Africa CDC or the African Union**.







## B. New guidelines and resources

Since 3 October 2020,

- Africa CDC has published new guidance and resources on:
  - Joint WHO AFRO and Africa CDC Statement on the Use of Corticosteroid for the Management of Severe and Critical COVID-19 Cases;
  - Africa CDC COVID-19 Social Media Support Kit;
  - COVID-19 PANDEMIC RESPONSE INITIATIVES
- US CDC has published new guidance and resources on:
  - <u>Commercial Laboratory Seroprevalence Surveys;</u>
    - <u>Clinical Questions about COVID-19: Questions and Answers;</u>
    - Scientific Brief: SARS-CoV-2 and Potential Airborne Transmission;
    - Evidence used to update the list of underlying medical conditions that increase a person's risk of severe illness from COVID-19;
    - Travel during the COVID-19 Pandemic;
    - <u>Clinical decision algorithm to guide care advice messages;</u>
    - <u>Considerations for Optimizing the Supply of Powered Air-Purifying</u> <u>Respirators (PAPRs)</u>;
    - <u>CDC's Interim Guidance for General Population Disaster Shelters</u> <u>During the COVID-19 Pandemic;</u>
    - Flowchart for management of HCWs with exposure to a person with COVID-19;
    - <u>Case Series of Multisystem Inflammatory Syndrome in Adults</u> <u>Associated with SARS-CoV-2 Infection — United Kingdom and United</u> <u>States, March–August 2020;</u>
    - Strategies for Optimizing the Supply of Isolation Gowns;
    - <u>Wildfire Smoke and COVID-19: Frequently Asked Questions and</u> <u>Resources for Air Resource Advisors and Other Environmental Health</u> <u>Professionals:</u>
  - <u>Elastomeric Respirators: Strategies During Conventional and Surge</u> <u>Demand Situations;</u>
  - <u>Sharing and Shifting Tasks to Maintain Essential Healthcare During</u> <u>COVID-19 in Low Resource, non-US settings;</u>
  - Guidance for SARS-CoV-2 Point-of-Care Testing;
  - Vaccines;
  - <u>Considerations for Monitoring and Evaluation of Mitigation Strategies</u> <u>Implemented in Institutions of Higher Education;</u>
  - Information for Laboratories about Coronavirus (COVID-19);
  - <u>Case Investigation and Contact Tracing in Non-healthcare</u> Workplaces: Information for Employers;







- <u>Treatments Your Healthcare Provider Might Recommend for Severe</u> <u>Illness;</u>
- <u>Contact Tracing by Community Health Workers in Low-Resource,</u> <u>Non-US Settings;</u>
- WHO has published new guidance and resources on:
  - <u>Handbook for public health capacity-building at ground crossings and</u> <u>cross-border collaboration;</u>
  - Log of major changes and errata in WHO daily aggregate case and death count data;
  - <u>The impact of COVID-19 on mental, neurological and substance use</u> <u>services</u>
- FDA has issued press releases on:
  - FDA Issues Guidance on Emergency Use Authorization for COVID-19 Vaccines;
- ECDC has issued new resource on:
  - Influenza during the COVID-19 pandemic protect yourself and others from COVID-19 during influenza vaccination;
  - Influenza during the COVID-19 pandemic why it's important to get vaccinated against influenza;
  - Infographic: Infection prevention and control in primary care;
  - Leaflet: Mother-to-child transmission of COVID-19;
  - Download data on country response measures to COVID-19; Indicators for the maps in support of the Council Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the EU/EEA and the UK;
  - <u>Guidance for discharge and ending of isolation of people with COVID-</u><u>19;</u>
- PHE has issued new resource on:
  - <u>COVID-19: guidance on supporting children and young people's</u> mental health and wellbeing;
  - <u>COVID-19: cleaning of non-healthcare settings outside the home;</u>
  - <u>COVID-19: guidance for commissioners and providers of services for people who use drugs or alcohol;</u>
  - COVID-19: how to work safely in domiciliary care in England
- IFRC has issued new resources on:
  - <u>The importance of mental health and psychosocial support during</u> <u>COVID-19</u>

The full list of latest guidance and resources from WHO and other public health institutions can be found in this <u>link</u>.







## C. Scientific updates

#### **Basic Science**

- A cross-sectional, case-control, sub-study of 136 Health Care Workers (HCWs) with mild or asymptomatic infection reports on the T cell responses and presence of neutralizing antibodies after the first wave. <u>Neutralising</u> antibodies (nAb) were present in 90% of infected HCW samples after the first wave; titres, likely to correlate with functional protection, which were present in 66% of HCW. T cell responses tended to be lower in asymptomatic infected HCW than those reporting case-definition symptoms of COVID-19, while nAb titres were maintained irrespective of symptoms. (Not Peer Reviewed)
- This study suggests a direct relationship between COVID-19 disease severity, and the levels of circulating SARS-CoV-2-specific antibodies, including virus neutralizing titers. <u>Results indicate that SARS-CoV-2-specific and virus-</u> neutralizing antibody levels were elevated in individuals that experienced severe disease with an increase in SARS-CoV-2-specific antibody dominated by IgG. Authors propose that Spike-specific IgG3 subclass utilization contributes to COVID-19 disease severity and these results have significant implications for SARS-CoV-2 vaccine design, and convalescent plasma therapy. (Not Peer Reviewed)
- Phylogenetic analysis of 274 SARS-CoV-2 genomes from samples collected during the early phase of the pandemic in Kenya identified 8 global lineages and at least 76 independent SARS-CoV-2 introductions into the Kenyan coast. The dominant B.1 lineage (European origin) accounted for 82.1% of the cases while lineages A, B and B.4 detected from screened individuals at the Kenya-Tanzania border or returning travellers did not lead to established transmission. None of the introduced lineages showed extensive local expansion other than cases characterised by lineage B.1, which accounted for 45 of the 76 introductions. Authors conclude that the international points of entry were important conduits of SARS-CoV-2 importations. (Not Peer Reviewed)
- This study quantified olfactory functions in asymptomatic COVID-19 patients using an olfactory-action meter that determines detectability indices at different odour concentrations. <u>Measurement of detection indices at low</u> <u>concentrations revealed a 50% reduction in asymptomatic COVID-19</u> <u>carriers thereby identifying 82% of the asymptomatic SARS-CoV-2 carriers</u> <u>with olfactory deficits. Findings suggest that compromised olfactory fitness</u> <u>can serve as a strong basis for identifying asymptomatic COVID-19 patients.</u>

#### Epidemiology

 A web-based cross-sectional study reports on the prevalence and risk of suicidal behavior among the general population and Health Care Providers (HCPs) in Bangladesh. There were 3,388 respondents who took part in the survey and among them, 834 were frontline HCPs. <u>Results indicate that about</u> 6.1% of the total participants had suicidal behaviour, with no detectable differences within the groups. Regression analysis showed that being female, being divorced, and having no child emerged as independent predictors for suicidality. A majority of the participants sometimes had fear of death although no significant relation of the factor was found with suicidality.







- This cohort study followed the first 101 neonates born to mothers with perinatal SARS-CoV-2 infections at a single institution in New York City to determine the risk of mother-to-newborn transmission of SARS-CoV-2. <u>2% of neonates had positive test results but none had clinical evidence of COVID-19. These findings suggest that during the COVID-19 pandemic, separation of affected mothers and newborns may not be warranted, and direct breastfeeding appears to be safe.
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- A cross-sectional study conducted among 301 randomly selected residents of Addis Ababa; with no known history of contact with confirmed COVID-19 person, reports on the sero-prevalence of SARS-CoV-2 in Addis Ababa. <u>The SARS-CoV-2 sero prevalence was estimated at 8.8% for the study population</u> with a higher sero prevalence observed for males (9.0%). According to the findings, possibly more individuals had been infected in Addis Ababa than what was being detected and reported by RT-PCR test suggestive of community transmission. (Not Peer Reviewed)
- This cross-sectional study examined the SARS-CoV-2 antibody prevalence among 790 university students in Los Angeles, California. <u>The estimated</u> prevalence of SARS-CoV-2 antibody was 4.0% with a history of anosmia and/or loss of taste being factors associated with a positive test result. The study concludes that the prevalence of SARS-CoV-2 antibodies in the undergraduate and graduate student university population was similar to community prevalence.
- This community-based cross-sectional study conducted among 844 pregnant women assessed the maternal health care services utilization amid the COVID-19 pandemic in West Shoa Zone, Central Ethiopia. <u>The prevalence of maternal health service utilization during the COVID-19 pandemic was 64.8%</u>. Results indicate that the odds of utilizing maternal health service were higher among mothers who did not fear COVID-19 infection, who had practiced COVID-19 prevention measures and used face masks than their counterparts. Findings suggest that empowering mothers and creating awareness on the COVID-19 prevention is recommended to improve maternal health service utilization during the COVID-19 pandemic. (Not Peer Reviewed)
- This cross sectional study assessed the determinants of COVID-19 disease severity among 686 COVID-19 patients admitted to Millennium COVID-19 Care Center in Ethiopia. <u>Results indicate that being old, male, and having</u> hypertension, diabetes mellitus, and symptoms of fever and headache were found to be determinants of developing a more severe COVID-19 disease. Authors recommend better preventive practices to be put in place to protect these groups of patients from infection and a more careful follow-up and management should be given to prevent complications and death for those who are already infected. The study further suggests the importance of considering the above non respiratory symptoms as disease severity indicators. (Not Peer Reviewed)
- A prospective cohort study was conducted among a randomly selected sample of 360 COVID-19 patients to estimate time to recovery/convalescence and identify determinants among COVID-19 infected patients admitted to Millennium COVID-19 Care Center in Addis Ababa, Ethiopia. <u>The Median</u> time to recover among the study population was 16 days. Presence of







symptoms was found to be associated with delayed viral clearance (44% lower rate of achieving recovery than asymptomatic patients).Findings suggest that attention should be given in the isolation and treatment practice of COVID-19 patients with regard to presence of symptoms. (Not Peer Reviewed)

 An observational prospective monocentric study reports on the manifestation of COVID-19 in 44 people living with HIV (PLWH). Of the 44 PLWH that tested positive for COVID-19, 14 (25.9%) developed a severe form of COVID-19 and 5 (9.3%) were critical cases. By multivariate analysis, age, male sex, ethnic origin from sub-Saharan Africa and metabolic disorder were associated with severe or critical forms of COVID-19. Prior CD4+ T cell counts did not differ between groups. No protective effect of a particular antiretroviral class was observed.

#### Care and Treatment

- This randomised, controlled, open-label, platform trial (RECOVERY trial) reports on whether lopinavir-ritonavir improves outcomes in patients admitted to hospital with COVID-19. <u>Results indicate in patients admitted to the hospital with COVID-19</u>, lopinavir-ritonavir was not associated with reductions in 28-day mortality, duration of hospital stay, or risk of progressing to invasive mechanical ventilation or death. These findings do not support the use of lopinavir-ritonavir for treatment of patients admitted to hospital with COVID-19.
- The interim WHO SOLIDARY trial results indicate that <u>Remdesivir</u>, <u>Hydroxychloroquine</u>, <u>Lopinavir</u> and <u>Interferon</u> regimens appeared to have <u>little or no effect on hospitalized COVID-19</u>, as indicated by overall mortality, initiation of ventilation and duration of hospital stay.

#### Economic Studies

- This study estimates the per patient per day unit costs of COVID-19 case management for patients that are asymptomatic and those that have mild to moderate, severe, and critical symptoms. <u>Results indicate the per day per patient unit cost for asymptomatic patients and patients with mild to moderate disease under home based care are USD 18.89 and USD 18.99 respectively and USD 70.29 and USD 70.31 respectively when managed in an isolation center of hospital. Per day unit costs for patients with severe disease managed in general hospital wards and those with critical disease admitted in intensive care units are USD 119.16 and USD 562.79. (Not Peer Reviewed)
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- A dynamic COVID-19 microsimulation model was developed to evaluate clinical and economic outcomes and cost-effectiveness of epidemic control strategies in KwaZulu-Natal, South Africa. Interventions assessed were Healthcare Testing (HT), Contact Tracing (CT); Isolation Centres (IC); Mass Symptom Screening and molecular testing for symptomatic individuals (MS); and Quarantine Centres (QC). <u>Findings indicate that strategies involving CT</u>, IC, mass symptom screening, and QC for contacts who test negative would substantially reduce COVID-19 mortality and be cost-effective. The optimal combination of interventions, however, depends on epidemic growth







characteristics and practical implementation considerations. (Not Peer Reviewed)

#### Diagnostics

- This study evaluated an antibody detection approach utilizing the OraSure Technologies' Oral Antibody Collection Device (OACD) and their proprietary SARS-CoV-2 total antibody detection ELISA. <u>Results indicate that the</u> <u>OraSure test for total antibody detection in oral fluid had comparable</u> <u>sensitivity and specificity to serum-based ELISAs while presenting a more</u> <u>affordable and accessible system with the potential for self-collection.</u> (*Not* <u>Peer Reviewed</u>)
- This study reports on the sensitivity and efficiency of SARS-CoV-2 detection in 79 clinical samples collected directly into a mix of lysis buffer supplemented with nucleic acid stabilization mix (NSLB) and RNA preservative. <u>Results</u> indicate that RT-qPCR tests of patients were significantly more sensitive with NSLB sampling, reaching detection threshold 2.1±0.6 PCR cycles earlier than VTM samples from the same patient. Overall, this study suggests that using NSLB instead of VTM can improve the sensitivity, safety, and rapidity of COVID-19 tests at a time most needed. (Not Peer Reviewed)
- This study reports on the sensitivity and specificity of a Specific Enhancer for PCR-amplified Nucleic Acid (SENA) which was developed based on the Cas12a trans-cleavage activity specifically triggered by the rRT-PCR amplicons of the SARS-CoV-2 Orf1ab (O) and N fragments. <u>Findings indicate</u> that SENA increases both the sensitivity and the specificity of rRT-PCR, solving the uncertainty problem in COVID-19 diagnosis and thus providing a simple and low-cost companion diagnosis for combating the pandemic.

#### Vaccines

- A placebo-controlled, observer-blinded, dose-escalation, phase 1 trial conducted in the United States reports on the safety and immunogenicity of the COVID-19 vaccine candidates BNT162b1 and BNT162b2. Of the 195 participants that underwent randomization, 156 received a vaccine while 39 received a placebo. <u>BNT162b2 was associated with a lower incidence and severity of systemic reactions than BNT162b1, particularly in older adults. The study supports the selection of BNT162b2 for advancement to a pivotal phase 2–3 safety and efficacy evaluation.
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- This study describes the efforts to utilize an mRNA platform for rational design and evaluations of mRNA vaccine candidates based on Spike (S) glycoprotein of SARS-CoV-2. <u>The selected 2P/GSAS vaccine formulation</u>, now designated MRT5500, elicited potent neutralizing antibodies as measured in two types of neutralization assays. The findings position MRT5500 as a viable vaccine candidate for clinical development against COVID-19. (Not Peer Reviewed)
- This randomised, double-blind, placebo-controlled, phase 1/2 trial assessed the safety and immunogenicity of an inactivated SARS-CoV-2 vaccine candidate, BBIBP-CorV, in humans in China. <u>Results indicate that the</u> <u>inactivated SARS-CoV-2 vaccine</u>, BBIBP-CorV, is safe and well tolerated at







all tested doses (4 µg and 8 µg) in two age groups (18-59 years and  $\geq$ 60 years). Findings indicate that humoral responses against SARS-CoV-2 were induced in all vaccine recipients on day 42.

 This study reports on the safety and efficiency of a rabies virus-based vector COVID-19 vaccine. <u>The results indicate that both a live and an inactivated</u> rabies virus containing the SARS-CoV-2 spike S1 protein induces potent virus-neutralizing antibodies at much higher levels than seen in the sera of convalescent patients. Findings of this study warrant further development of this safe and established vaccine platform against COVID-19.

#### Other

This study focuses on the modelling and the forecasting of COVID-19 spread in the most affected African countries (Morocco, Algeria, Tunisia, Egypt and South Africa) and for the sake of comparison two of the most affected European countries were also considered (France and Italy). An epidemiological SEIQRDP model is presented which considers quarantine in order to better coincide with the preventive measures taken by the governments to deal with the spread of COVID-19. The results show that the number of infections due to the use of quarantine is expected to be very low provided the isolation is effective. However, numbers are increasing in some countries with the early lifting of containment. The information provided by the model could help to establish a realistic assessment of the short-term pandemic situation and this will help maintain the most appropriate and necessary public health measures after the lockdown lifting. (Not Peer Reviewed)







#### D. Summary of travel restrictions implemented by Member States

Contents of this section include only publicly announced public health policies. Sources of this section include official government communique, embassy alerts and press search. (As of 18 October 2020)



1 Some countries still allow cargo, freight and emergency transport into and out of the country; Some MSs will

still allow citizens and residents to enter but all borders are essentially closed Entry or exit of passengers through COVID-19 screening 2

For further detailed information for each country, refer to the full table here.

## E. Summary of border control measures and school re-opening Contents of this section include only publicly announced public health policies. Sources of this section include official government communique, embassy alerts and press search. (As of 18 October 2020) **Borders** School Reopening

**Commercial passenger flights** 

Open land and sea boarders

Screening measures\*\*



**Closure of country-wide** educational institutions

# of Member States that 📕 Have implemented Have not implemented \*Source of information based on official reports, embassy alerts and press scanning

\*\*Only countries with open commercial flights included

For further detailed information for each country, refer to the full table here.







#### E. Clinical Trials Updates Key updates:

Vaccine trials:

- On 15 October 2020, Regulatory Affairs Professionals Society (RAPS) published that China's CanSino Biologics has developed a recombinant novel coronavirus vaccine that incorporates the adenovirus type 5 vector (Ad5). Preliminary safety data from a Phase 1 (ChiCTR2000030906; NCT04313127) clinical trial of 108 participants between 18 and 60 years old who will receive low, medium, and high doses of Ad5-nCoV has allowed the company to plan to initiate a Phase 2 trial, according to an <u>announcement</u>. The Phase 2 (ChiCTR2000031781) trial has identical inclusion criteria.
- A single dose of Ad5-nCoV protected against upper respiratory infection of SARS-CoV-2 in ferrets, according to a paper published on 14 August in Nature Communications. Results from the Phase 1 trial show a humoral and immunogenic response to the vaccine, according to a paper published in The Lancet. Adverse reactions such as pain (54%), fever (46%), fatigue (44%), headache (39%), and muscle pain (17%) occurred in 83% of patients in the low and medium dose groups and 75% of patients in the high dose group. In the Phase 2 trial, neutralizing antibodies and specific interferon γ enzyme-linked immunospot assay responses were observed at all dose levels for most participants. The Phase 3 trial is underway at sites in Saudi Arabia and Russia.
- On 15 October 2020, Regulatory Affairs Professionals Society(RAPS) published that Researchers at Sinopharm and the Wuhan Institute of Virology under the Chinese Academy of Sciences are developing an inactivated COVID-19 vaccine candidate. They have initiated a randomized, double-blind, placebo parallel-controlled Phase 1/2 clinical trial (ChiCTR2000031809) of healthy individuals starting at 6 years old. The vaccine has shown a "strong neutralizing antibody response" in Phase 1/2 trials, according to a release from China National Biotic Group. Results from a Phase 1 and a Phase 2 trial published in JAMA show the vaccine candidate has demonstrated immunogenicity. Phase 3 trials are underway in Peru, Morocco, and in the United Arab Emirates.
- On 15 October 2020, Regulatory Affairs Professionals Society(RAPS) published that Bharat Biotech, an Indian biotechnology company, is partnering with the National Institute of Virology to develop an inactivated vaccine candidate for COVID-19 called Covaxin. A Phase 1/2 trial of about 1,100 healthy participants is <u>underway</u> after <u>approval</u> by the Drug Controller General of India. In addition to Covaxin, Bharat Biotech is working on two other vaccine candidates: one with the <u>University of Wisconsin–Madison</u> and FluGen, and the other with <u>Thomas Jefferson</u> <u>University.</u>
- Results of a two-dose regimen given to rhesus macaques <u>posted</u> to the pre-print server Research Square showed an increase in SARS-CoV-2 specific IgG and neutralizing antibodies and reduced viral replication in the nasal cavity, the throat, and the lung. Early <u>results in</u> the first 50 people who received the vaccine candidate appear to be "encouraging," according to a comment from the trial's principal investigator. The Indian Council of Medical Research has reported covaxin candidate has <u>entered</u> Phase 2 trials.







Therapeutics trials:

- On 16 October 2020, Biotech company ANA Therapeutics announced that Niclosamide, an antiparasitic drug used to manage tapeworm infections, is being investigated by several centers as a COVID-19 therapeutic. Biotech company ANA Therapeutics is <u>evaluating niclosamide in capsule form under the name ANA001</u> in a clinical trial authorized by the FDA. Niclosamide is also being investigated in a randomized Phase 2 trial of 100 participants with mild-to-moderate COVID-19 at Tufts Medical Center (NCT04399356), a Phase 2 trial of 100 participants with moderate COVID-19 sponsored by First Wave Bio, Inc. (NCT04436458), and at Lille University Hospital in France in combination with diltiazem against hydroxychloroquine and standard of care (NCT04372082) The drug is also being tested in a <u>Phase 1 trial in the</u> Philippines, <u>South Korea</u>, and India by Daewoong Pharmaceutical.
- On 16 October 2020, NeuroRX announced Early results from the first 30 patients enrolled in the COVID-AIV trial and these results shown no significant drug-related adverse events among patients taking RLF-100 compared with placebo.
   <u>Topline results</u> from an open-label, prospective study show survival of 81% for patients hospitalized for COVID-19 who received RLF-100 compared with the placebo group.
   RLF-100 is thought by researchers to help decrease mortality and improve oxygenation in the blood for patients with COVID-19 through its anti-inflammatory activity. It currently has an Orphan Drug designation from the FDA and EMA for acute lung injury. NeuroRx is planning several clinical trials for RLF-100: the 144-person AVINALI study evaluating the candidate's effectiveness in treating non-acute lung injury (NCT04360096), and the COVID-AIV trial evaluating patients with critical COVID-19 who have respiratory failure (NCT04311697). FDA has also granted Expanded Access Protocol for patients ineligible for enrollment in COVID-AIV (NCT04453839).
- On 16 October 2020, it was announced that Sorrento Therapeutics is testing a tyrosine kinase inhibitor STI-5656 (abivertinib maleate) in patients hospitalized with COVID-19 related pneumonia. The company recently licensed abivertinib from ACEA Therapeutics for use as a therapy for COVID-19. The FDA has approved a Phase 2 trial of 80 participants receiving STI-5656 or standard of care (NCT04440007), and a Phase 2 trial of up to 400 participants is planned in Brazil (NCT04528667).
- On 16 October 2020, Celltrion announced that Interim data from the Phase 1 trial indicate that CT-P59 is safe and tolerable without any adverse events. Celitrion, based in South Korea, is evaluating the human monoclonal antibody CT-P59 as a potential treatment for COVID-19. The candidate was selected through a screening process where CT-P59 was found to neutralize the SARS-CoV-2 and several variants such as the mutated G-variant strain (D614G). <u>A Phase 1 trial of up to 32 participants is underway (NCT04525079)</u>. The Korean Ministry of Food and Drug Safety (MFDS) approved a phase 2/3 trial in up to 1,000 patients in 12 countries in September, and a Phase 3 trial in up 1,000 participants evaluating the post-exposure prophylaxis of the candidate has been approved by MDFS.
- Lenzilumab has been shown to have a protective effect against cytokine release syndrome associated with CAR-T therapy. It's believed that lenzilumab can aid cytokine-mediated immunopathology of lung injury and ARDS. A multicenter, Phase 3, randomized, double-blinded, controlled, clinical trial with lenzilumab for the prevention of ARDS in patients with pneumonia associated with COVID-19 (NCT04351152), which is taking place in the U.S. and Brazil. Lenzilumab is







being evaluated in NIAID's Big Effect trial in combination with Veklury compared with Veklury plus a placebo (NCT04583956). Early results from the first 12 patients who received lenzilumab at Mayo Clinic locations showed 11 of 12 (92%) had clinical improvement, with a median discharge time of 5 days. Oxygenation also was improved in patients taking lenzilumab. Further results <u>published in Mayo Clinic</u> Proceedings showed lenzilumab was associated with an 80% reduction in risk of mechanical ventilation and mortality.

#### For further detailed information for each country, refer to the full table here

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