





COVID-19 Scientific and Public Health Policy Update¹ – (02 February 2021)

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 not intended to serve as recommendations 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

- Sallam et al. report on the SARS-CoV-2 S gene sequences collected in the Middle East and North Africa (MENA) suggest that the D614G mutation appeared to be taking over the COVID-19 infections in the MENA. Further, the bayesian analysis suggested that SARS-CoV-2 might have been circulating in MENA earlier than previously reported.
- Wibmer et al. show that the SARS-CoV-2 501Y.V2, a novel lineage of the coronavirus causing COVID-19, exhibits complete escape from three classes of therapeutically relevant monoclonal antibodies. Furthermore, 501Y.V2 shows substantial or complete escape from neutralizing antibodies in COVID-19 convalescent plasma.
- Mashe et al. report on 100 sequenced SARS-CoV-2 samples from patients in Zimbabwe determined their relationship to one another and Whole Genome Sequences from global samples. Eight lineages, from at least 25 separate introductions into the region were found and early introductions and spread of SARS-CoV-2 were predominantly associated with genomes common in Europe and the US, and few common in Asia.
- Nath et al. performed computational docking studies to determine shared antigenic similarity between SARS-CoV-2 and dengue virus (DV). Results predicted with high confidence that human DV antibodies can indeed bind to RBD of SARS-CoV-2 Spike protein.
- Butler-Laporte et al. conducted a systematic review which assessed the diagnostic accuracy of saliva NAAT for COVID-19 compared with imperfect nasopharyngeal swab NAAT as a reference test. Findings suggest that saliva NAAT diagnostic accuracy is similar to that of nasopharyngeal swab NAAT, especially in the ambulatory setting.
- Nakabayashi et al. evaluated the detection sensitivity of RT-PCR performed using synthetic RNAs containing frequently observed mutations. Results showed that certain primer/probe-template mismatches significantly decreased the sensitivity of RT-PCR assays. Not peer reviewed

¹ 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 Africa Union**.







B. New guidelines and resources

Since 14 December 2020,

- Africa CDC has published new guidance and resources on:
 - New SARS-CoV-2 variants in Africa;
 - <u>Guidance on Emergency Expedited Regulatory Authorisation and</u> Access to COVID-19 Vaccines in Africa;
 - <u>Interim Guidance on the Use of Rapid Antigen tests for COVID-19</u> Response
- US CDC has published new guidance and resources on:
 - <u>Prioritizing Case Investigations and Contact Tracing for COVID-19 in</u> High Burden Jurisdictions
 - How to Make 0.1% Chlorine Solution to Disinfect Surfaces in Healthcare Settings
 - How to mitigate COVID-19 transmission in densely populated areas globally
 - Strategies for Protecting K-12 School Staff from COVID-19
 - Providing Care and Treatment for People Living with HIV in Low-Resource Non-US Settings During COVID-19 Pandemic
 - COVID-19 Rapid Response Team Guidance
 - Considerations for Events and Gatherings
 - Operating schools during COVID-19: CDC's Considerations
 - Providing Care and Treatment for People Living with HIV in Low-Resource Non-US Settings During COVID-19 Pandemic
 - Testing Guidelines for Nursing Homes
 - <u>Interim Guidelines for Collecting, Handling, and Testing Clinical</u> Specimens for COVID-19
 - Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
 - <u>Guidance for Cleaning and Disinfecting Public Spaces, Workplaces,</u> <u>Businesses, Schools, and Homes</u>
 - Suggestions for Youth and Summer Camps
 - Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan: Overview
 - Guidance for Businesses and Employers Responding to Coronavirus

 <u>Disease 2019 (COVID-19)</u>
 - Considerations for Non-emergency Vehicle Transportation for Tribal
 Communities During COVID-19
 - Considerations for Retirement Communities and Independent Living
 Facilities
 - Considerations for Community-Based Organizations
 - Healthcare Facilities: Managing Operations During the COVID-19
 Pandemic







- Standard Operating Procedure (SOP) for Triage of Suspected
 COVID-19 Patients in non-US Healthcare Settings: Early
 Identification and Prevention of Transmission during Triage
- Interim Guidance for Antigen Testing for SARS-CoV-2
- CDC Guidance for Expanded Screening Testing to Reduce Silent Spread of SARS-CoV-2
- WHO has published new guidance and resources on:
 - <u>Interim recommendations for use of the Pfizer–BioNTech COVID-19</u> vaccine, BNT162b2, under Emergency Use...
 - Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health
 - SARS-CoV-2 genomic sequencing for public health goals: Interim guidance, 8 January 2021
 - <u>Infection prevention and control guidance for long-term care facilities</u> in the context of COVID-
 - Statement of the WHO Working Group on COVID-19 Animal Models (WHO-COM) about the UK
- FDA has issued press releases on:
 - FDA Statement on Following the Authorized Dosing Schedules for COVID-19 Vaccines
 - COVID-19 Vaccines
 - FDA authorized 311 tests under Emergency Use Authorizations (EUAs); these include 235 molecular tests, 64 antibody tests and 12 antigen tests as of January 8, 2021. The FDA continues to monitor authorized tests and emerging scientific evidence and may revise or revoke an EUA, when appropriate, including when a test's benefits no longer outweigh its risks. The FDA provides continuous updates to make clear which tests have been issued EUAs by the agency, and which tests should not be used
- ECDC has issued new resource on:
 - Strategic and performance analysis of ECDC response to the COVID-19 pandemic
 - Communicable disease threats report, 3-9 January 2021, week 1
 - Communicable disease threats report, 27 December-2 January 2020, week 53
 - Risk related to spread of new SARS-CoV-2 variants of concern in the EU/EEA
- PHE has issued new resource on:
 - <u>COVID-19</u>: investigation and initial clinical management of possible cases
 - <u>COVID-19</u>: management of staff and exposed patients and residents in health and social care settings







<u>COVID-19: guidance for stepdown of infection control precautions</u> within hospitals and discharging COVID-19 patients from hospital to home settings

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

C. Scientific updates

Basic Science

- The SARS-CoV-2 S gene sequences collected in the Middle East and North Africa (MENA) were retrieved from the GISAID public database, together with its metadata to identify mutations in the S gene among SARS-CoV-2 sequences focusing on the D614G mutation. Results indicate that there was a significant increase in the proportion of D614G from 63.0% in February 2020, to 98.5% in June 2020. Findings suggest that the D614G mutation appeared to be taking over the COVID-19 infections in the MENA. Further, the bayesian analysis suggested that SARS-CoV-2 might have been circulating in MENA earlier than previously reported.
- Researchers investigated the kinetics of SARS-CoV-2 neutralizing antibodies during the 5 months after infection in asymptomatic persons and patients with pneumonia caused by SARS-CoV-2. The geometric mean titer of neutralizing antibodies declined from 219.4 at 2 months to 143.7 at 5 months after infection with neutralizing antibody titer decreasing more in symptomatic than asymptomatic patients. Findings demonstrate waning humoral immunity in patients with SARS-CoV-2 infection thereby reinforcing the concern that naturally acquired humoral immunity against SARS-CoV-2 might not be long-lasting.
- This study shows that the SARS-CoV-2 501Y.V2, a novel lineage of the coronavirus causing COVID-19, contains multiple mutations within two immune-dominant domains of the spike protein. This lineage exhibits complete escape from three classes of therapeutically relevant monoclonal antibodies. Furthermore, 501Y.V2 shows substantial or complete escape from neutralizing antibodies in COVID-19 convalescent plasma. These data highlight the prospect of reinfection with antigenically distinct variants and may foreshadow reduced efficacy of current spike-based vaccines. (Not peer reviewed)
- Researchers sequenced SARS-CoV-2 samples from 100 patients collected over the period of March to June 2020 in Zimbabwe to determine their relationship to one another and Whole Genome Sequences from global samples. Eight lineages, from at least 25 separate introductions into the region were found using comparative genomics. Of these, 95% had the D614G mutation on the spike protein which was associated with higher transmissibility than the ancestral strain. Early introductions and spread of SARS-CoV-2 were predominantly associated with genomes common in Europe and the US, and few common in Asia at this time. (Not peer reviewed)
- Researchers performed computational docking studies to test if SARS-CoV-2 and dengue virus (DV) might share antigenic similarity. Results predicted







with high confidence that human DV antibodies can indeed bind to RBD of SARS-CoV-2 Spike protein. Findings suggest it is highly probable that immunological memory/antibodies to DV in endemic countries may reduce the severity and spread of COVID-19.

Epidemiology

- A prospective cohort study of 4,040 HCWs in Cairo, Egypt examined SARS-CoV-2 seroconversion incidence and its risk factors 21 days after baseline screening in a resource-limited setting. Results indicate that seroconversion was 4.0% among asymptomatic and 5.3% among symptomatic HCWs and seropositivity was three-fold that observed at baseline. Findings suggest that the cumulative infections increased nationally by a similar rate, suggesting that HCWs' infections reflect community not nosocomial transmission during the first wave of COVID-19 epidemic in Egypt.
- A study of postmortem viral RNA stability was conducted to determine the
 possibility of SARS-CoV-2 transmission through deceased persons. Results
 demonstrated maintained infectivity of SARS-CoV-2 in tissues of deceased
 patients and the SARS-CoV-2 RNA persisted over time at constantly high
 titers. Findings of nasopharyngeal viral RNA stability in 79 corpses showed
 no time-dependent decrease and maintained infectivity is supported by virus
 isolation up to 35 hours postmortem.
- This study determines risk factors for death in patients with COVID-19 admitted to the main public sector hospital in Somalia and identifies interventions contributing to improved clinical outcome in a low-resource and fragile setting. This study confirms that underlying conditions and age are associated with increased risk of in-hospital death in patients with COVID-19. Results show the advantage of medical oxygen over non-invasive ventilation in the treatment of patients with severe COVID-19 symptoms. (Not peer reviewed)
- This study compared SARS-CoV-2 seroprevalence amongst HCWs in paediatric facilities in eight countries. The overall seroprevalence range was 0-16.93%. The highest seroprevalence was 16.93% in London followed by that in Cape Town, South Africa at 10.36%. Findings suggest the overall seroprevalence amongst paediatric HCWs is similar to their national populations and linked to national COVID-19 burden and staff working in paediatric facilities in low burden countries have very low rates of seroprevalence and thus are likely to be susceptible to COVID-19.
- This mathematical model describes SARS-CoV-2 transmission and disease progression in the presence of vaccination in Qatar. Results indicate that for a vaccine that protects against infection with an efficacy of 95%, half as many vaccinations were needed to avert one infection, disease outcome, or death by prioritizing antibody-negative individuals for vaccination. Prioritization by antibody status reduced incidence at a faster rate and led to faster elimination of infection and return to normalcy. Findings suggest that major health, societal, and economic gains can be achieved more quickly by prioritizing those who are antibody-negative while doses of the vaccine remain in short supply. (Not peer reviewed)







- A pilot, randomized, double-blind, placebo-controlled trial evaluated the
 efficacy of a single dose of ivermectin to reduce the transmission of SARSCoV-2 when administered early after disease onset. Results failed to show a
 reduction in the proportion of PCR-positive patients seven days after
 ivermectin treatment; yet it showed a reduction in the self-reported
 anosmia/hyposmia and a (non-statistically significant) tendency to lower
 viral loads and lower IgG titers which presumably reflect milder disease.
- A randomized, double-blind, placebo-controlled trial evaluated whether convalescent plasma with high SARS-CoV-2 antibody titers, administered within 72 hours after the onset of mild symptoms, would be efficacious in preventing progression to severe disease in older adult patients with Covid-19. <u>Findings indicate that early administration of high-titer convalescent</u> <u>plasma against SARS-CoV-2 to mildly ill infected older adults reduced the</u> <u>progression of Covid-19.</u>

Diagnostics

- This systematic review was conducted to assess the diagnostic accuracy of saliva NAAT for COVID-19 compared with imperfect nasopharyngeal swab NAAT as a reference test. In the primary analysis, the saliva NAAT pooled sensitivity was 83.2% and the pooled specificity was 99.2% while the nasopharyngeal swab NAAT had a sensitivity of 84.8% and a specificity of 98.9%. These results suggest that saliva NAAT diagnostic accuracy is similar to that of nasopharyngeal swab NAAT, especially in the ambulatory setting. These findings support larger-scale research on the use of saliva NAAT as an alternative to nasopharyngeal swabs.
- This study evaluated the detection sensitivity of RT-PCR performed using synthetic RNAs containing frequently observed mutations. <u>Results showed</u> that certain primer/probe-template mismatches significantly decreased the sensitivity of RT-PCR assays. Findings suggest the necessity of monitoring mutations in the viral genome sequence under in-silico conditions and evaluating the impact of mutations on diagnosis sensitivity to avoid false negatives. (Not peer reviewed)

Vaccines

- This multicenter, placebo-controlled, phase 1–2a trial evaluated the safety and reactogenicity of a candidate vaccine, Ad26.COV2.S in healthy adults. The interim analysis of the phase 1–2a trial shows that the Ad26.COV2.S vaccine has an acceptable safety and reactogenicity profile and is immunogenic after a single vaccination with either the low or high dose. The safety and immunogenicity profiles of Ad26.COV2.S support further development of this vaccine candidate.
- This study evaluated three different clinically tested adjuvant systems in combination with the SARS-CoV-2 pre-fusion stabilized (S-2P) spike protein using a one-dose regimen in mice. Results demonstrate that adjuvanted spike protein subunit vaccine is a viable strategy for rapidly eliciting SARS-CoV-2 neutralizing antibodies and CD4 T cell responses of various qualities depending on the adjuvant used, which can be explored in further vaccine development against COVID-19.







This cross-sectional online survey described the existing COVID-19 vaccine approval landscape among the health care providers and identified the most probable cause of agreement or disagreement of COVID-19 vaccine. 13.5%
totally agree to receive the vaccine, 32.4% somewhat agree and 40.9%
disagree with taking the vaccine. Causes of disagreement were safety, fear of genetic mutation and recent techniques and believe that the vaccine is not effective. Findings suggest that vaccine hesitancy is not uncommon in healthcare employees in Egypt and this may be an alarming barrier of vaccine acceptance in the rest of the population. There is an urgent need to start campaigns to increase the awareness of the vaccine importance. (Not peer reviewed)

D.

Other

- An online descriptive cross-sectional study used a partial proportional odds regression model to determine the predictors of anxiety among 273 undergraduate pharmacy students at the University of Zambia. Results indicate that 23.8% did not experience anxiety, 34.4% experienced mild anxiety, 24.9% experienced moderate anxiety while 16.9% experienced severe anxiety about COVID-19. It was also found that 61.2% of students reported that their attention to mental health increased during the COVID-19 pandemic. Findings suggest that COVID-19 negatively impacted the mental health and physical activity of pharmacy students at the University of Zambia and this can have negative health and academic outcomes for students going forward. Higher learning institutions and key stakeholders should implement measures to aid students to recover from the impact of COVID-19 on their mental health and physical activity. (Not peer reviewed)
- This study described the long-term health consequences of patients with COVID-19 who have been discharged from hospital and investigate the associated risk factors, in particular disease severity. At 6 months after acute infection, COVID-19 survivors were mainly troubled with fatigue or muscle weakness, sleep difficulties, and anxiety or depression. Patients who were more severely ill during their hospital stay had more severe impaired pulmonary diffusion capacities and abnormal chest imaging manifestations, and are the main target population for intervention of long-term recovery.

Clinical Trials Updates

Key updates:

Vaccine trials:

- On 31st December 2020 the World Health Organization granted emergency use validation to the Pfizer/BioNTech vaccine (manufactured as Comirnaty) the first to receive such approval. WHO said its emergency use listing opens the way for regulators in different countries to approve the import and distribution of the vaccine. It also enables UNICEF, which plays a key logistical role in distributing anti-Covid vaccines, and the Pan-American Health Organization, to procure the vaccine for countries that need it.
- On 30th December 2020, Oxford University/AstraZeneca vaccine was approved by UK medicines regulator (UK MHRA) for emergency use and roll out began on 4 January. The country has secured access to 100 million doses of the vaccine. The fact that it is stored at normal fridge temperature, as well as its low cost of around \$3 per dose, make the







AstraZeneca vaccine promising for tackling not only the UK's Covid-19 epidemic, but for helping to end the pandemic globally.

- On 31st December 2020, following further review of data for the Pfizer/BioNTech vaccine, the MHRA updated its recommendations indicating that 1) the vaccine should only be considered for use in pregnancy when the potential benefits outweigh any potential risks for the mother and baby; 2) that individuals with previous history of allergic reactions to the ingredients of the vaccine should not receive it and that 3) the booster dose could be delayed for up to 12 weeks after the primary dose.
- On 31st December 2020, China State Council Joint Prevention and Control Mechanism against COVID-19 announced conditional market approval had been granted by the National Medical Products Administration (NMPA), the Chinese equivalent of the US FDA for the BBIBP-CorV inactivated COVID-19 vaccine by Sinopharm. Conditional registration was approved based on interim results of phase-3 clinical trials showing a neutralizing antibody positive conversion rate of 99.52% & a protective efficacy against COVID-19 of 79.34 % although only limited details of phase 3 trial have been shared.
- Over 60,000 volunteers of 125 nationalities have participated in the Phase III clinical trial
 of Sinopharm CNBG in countries outside China including <u>UAE</u> and <u>Bahrain</u> with a reported
 efficacy of 86%. BBIBP-CorV vaccine doesn't require freezing temperatures for storage,
 which would make the vaccine transport and distribution easier for most of the
 countries. On January 15th, BBIBP-CorV was approved by <u>Pakistan</u> for emergency use.
- On 6th January 2021, the <u>European Commission granted the conditional marketing authorisation (CMA) for Moderna mRNA COVID-19 vaccine</u>, the second COVID-19 vaccine authorised in the EU following earlier authorization of Pfizer and BioNTech's Covid-19 vaccine in early December.
- On 25th January 2021, the Institut Pasteur in France announced that it was discontinuing the development of vaccine candidate based on the measles virus vaccine, following an interim analysis of the Phase I trials. The vaccine candidate was well tolerated, but elicited immune responses that were inferior to those seen after natural infection and those reported for currently authorized COVID-19 vaccines.
- On 28th January 2021, Novavax announced that interim analysis of the UK Phase 3 clinical trial of NVX-CoV2373, its protein-based COVID-19 vaccine candidate, demonstrated an efficacy of 89.3% (95% CI: 75.2 95.4) against RT-PCR-confirmed symptomatic COVID-19 (mild, moderate or severe). The analysis was based on 62 cases (56 cases in the placebo group vs 6 cases the vaccinated group) with more than 15,000 adults participants enrolled, including 27% over the age of 65. Efficacy by strain was reported to be 95.6% against the original COVID-19 strain and 85.6% against the 501Y.V1 SARS-CoV-2 variant strain which was circulating in UK during the study (over 50% of confirmed cases).
- On 29th January 2021, the <u>European Commission granted the conditional marketing</u> <u>authorisation for COVID-19 Vaccine AstraZeneca</u> to prevent coronavirus disease 2019 (COVID-19) in people from 18 years of age.
- On 29th January 2021, Johnson & Johnson announced interim efficacy and safety data of the Phase 3 ENSEMBLE trial of Ad.26.COV2.S (or JNJ-78436725), a recombinant human adenovirus vector vaccine expressing the SARS-CoV-2 spike protein, administered as a single dose. Protection against moderate to severe COVID-19 infection 28 days post-vaccination was 72% in the United States, 66% in Latin America and 57% in South Africa where 95% of COVID-19 cases were due to infection with the 501Y.V2 SARS-CoV-2 variant. Protection against severe disease was 85% across all regions studied 28 days after vaccination, with no case reported in vaccinated participants after day 49. Protection was generally consistent across race, age groups, including adults over 60 years of age.







In Africa,

- On 30th December 2020, <u>Guinea started Russian COVID-19 Vaccine (Sputnik V) trials</u>. The National Agency for Health Safety (ANSS) said 60 doses of the vaccine would be administered to middle-aged volunteers (50 and above) on a trial basis. Government officials were the first to receive the Sputnik V vaccine. The country will assess whether to extend the vaccinations to other regions following the pilot phase.
- On 24th December 2020, Morocco announced it had ordered 65 million doses of COVID-19 vaccines from China's Sinopharm and Britain's AstraZeneca, aiming to vaccinate 80% of the country's adult population. On 6th January 2021 <u>AstraZeneca COVID-19 vaccine was granted emergency use authorization by Morocco</u>'s regulators while <u>Sinopharm's vaccine was still under review</u> with approval for emergency use expected in the coming days. On 22nd January the Morocco <u>receptioned the first shipment of the British Astrazeneca vaccine</u>, manufactured in India, and on 28th January 2020, the <u>King launched the National Covid-19 Vaccination Campaign</u>.
- On 2nd January 2021, the Egyptian Health Minister Hala Zayed announced that the Egyptian Drug Authority (EDA) had granted approval for the emergency use of China Sinopharm vaccine.
- On 7th January 2021, <u>South Africa Minister of Health announced</u> that the country will be receiving one million doses (in January) and five hundred thousand doses (in February) of the Oxford university/AstraZeneca Vaccine from the Serum Institute of India (SII). The National Department of Health and the South African Health Products Regulatory Authority (SAHPRA) are aligning all the regulations processes. An estimated 1.25 million health care workers both from public and private will be prioritised
- On 7th January 2021, Kenya announced it had ordered 24 million doses of the COVID-19 vaccine developed by AstraZeneca. Kenya's health minister indicated that the country expects them to start arriving in the second week of February. The doses are being obtained through the COVAX facility and health workers and teachers will have priority for vaccinations
- On 10th January 2021, <u>Russia Direct Investment Fund (RDIF) announced that the National Agency of Pharmaceutical Products in Algeria had registered Gamaleya Institute Sputnik V COVID-19 vaccine</u> under the emergency use authorization procedure. Algeria is the first country in Africa to register the vaccine.
- On 19th January 2021, ImmunityBio announced the upcoming the phase I trial of its human adenovirus (hAd5) COVID-19 vaccine candidate in Cape town, South Africa (NCT04710303). ImmunityBio vaccine candidate is a next-generation adenovirus vaccine platform which can be administered either subcutaneously or orally. It targets both the mutation-prone outer spike protein (S) and the more stable inner nucleocapsid (N) protein, activating SARS-CoV-2 specific antibodies, memory B cells and T-cells. This vaccine has the potential to address mutations where other vaccines might fail, including the 501Y.V2 variant.
- On 28th January, 2021, Novavax announced that interim analysis of the Phase 2b clinical trial of NVX-CoV2373 in South Africa, demonstrated an efficacy of 60% (95% CI: 19.9 80.1) for the prevention of COVID-19 disease (mild, moderate or severe) in the study population that was HIV-negative (94% of over 4,400 patients enrolled). In the overall trial population (both HIV-positive and HIV-negative subjects) the reported vaccine efficacy was 49.4% (95% CI: 6.1 72.8). COVID-19 cases accounted in the analysis occured from September through mid-January, when the 501Y.V2 variant was prevalent, representing 92.6% of 27 sequenced cases (out of 44 cases total).
- On 29th January 2021, Russia Direct Investment Fund (RDIF) announced that the National Directorate of Pharmacy and Medicine of the Republic of Guinea had approved Gamaleya







<u>Institute Sputnik V vaccine</u>, becoming the second country in Africa to register the vaccine under the emergency use authorization procedure. On 30th January 2021, <u>Tunisia became the third country in Africa to register Sputnik V vaccine</u>, as the Ministry of Health also provided approval.

Therapeutics trials:

- On 22nd January 2021, the Montreal Heart Institute (MHI), in Canada announced that the randomized, double-blind, placebo-controlled COLCORONA clinical trial results which demonstrated that colchicine had reduced by 21% the risk of death or hospitalizations in patients with COVID-19 compared to placebo, preventing the cytokine storm and reducing the complications associated with COVID-19. In patients with RT-PCR confirmed COVID-19, colchicine reduced hospitalizations by 25%, the need for mechanical ventilation by 50%, and deaths by 44%. COLCORONA was conducted among approximately 4,500 COVID-19 patients not hospitalized at the time of enrolment.
- On 25th January 2021, Oxford University announced the interim results of the Platform Randomised trial of INterventions against COVID-19 In older peoPLE (PRINCIPLE) which indicated that azithromycin and doxycycline were not effective against COVID-19 in patients aged over 50 treated at home.
- On 22nd January 2021, the NIH reported data from a large clinical trials, which indicated that full dose anti-coagulation (blood thinner) treatments given to moderately ill patients hospitalized for COVID-19 reduced the requirement of vital organ support. Three trials spanning 5 continents have the common goal of assessing full doses of blood thinners to treat moderately ill or critically ill adults hospitalized for COVID-19 compared to lower doses: REMAP-CAP Therapeutic Anticoagulation, ACTIV-4 Antithrombotics Inpatient and ATTACC.

Immunotherapy trials:

- On 21st January 2021, Eli Lilly announced the Phase 3 BLAZE-2 COVID-19 prevention trial of Bamlanivimab (LY-CoV555), (dose 4,200 mg) conducted in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), among residents and staff of long-term care facilities (NCT04497987). After 8 weeks of follow-up of 965 participants, results indicated that the frequency of symptomatic COVID-19 (primary study endpoint) was significantly lower in the bamlanivimab treatment arm versus placebo (odds ratio 0.43, p=0.00021).
- On 26th January 2021, findings from Eli Lilly phase 3 BLAZE-4 trial, which assessed amlanivimab (LY-CoV555) 2800 mg and etesevimab (LY-CoV016) 2800 mg together for the treatment of high-risk patients recently diagnosed with COVID-19 (NCT04634409), demonstrated that COVID-19-related hospitalizations and deaths were signficantly reduced. Among 1035 patients evaluated, a 70 % risk reduction (p= 0.0004) was observed in patients taking therapy compared to those receiving placebo.
- On 26th January 2021, Regeneron announced positive initial results from the ongoing Phase 3 clinical trial of REGEN-COV[™] for the prevention of COVID-19 in household contacts of a COVID-19 patient. REGEN-COV[™] is a cocktail of casirivimab (REGN10933) and imdevimab (REGN10987) monoclonal antibodires, which, when used as passive vaccination confers short term passive immunity against SARS-CoV-2. Results of the trial indicated that REGEN-COV provided 100% prevention of symptomatic infection and approximately 50% lower overall rates of infection (symptomatic and asymptomatic). Furthermore, on 27th January 2021, Columbia







<u>University researchers</u> and <u>Regeneron</u> independently confirmed that REGEN-COV™ successfully neutralizes the circulating the 501Y.V1 SARS-CoV-2 variant first identified in the UK as well as the 501Y.V2 identified in South Africa. <u>Regeneron is collaborating</u> with Roche to increase global supply of REGEN-COV.

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

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