Largest clinical trial in Africa to treat mild COVID-19 cases launched in 13 countries

November 24 2020

Hospital Saint Joseph, DRC Credit: Kenny Mbala-DNDi

Thirteen African countries and an international network of research institutions have joined forces to launch the largest COVID-19 clinical trial in mild-to-moderate outpatients in Africa. The ANTICOV clinical

trial aims to respond to the urgent need to identify treatments that can be used to treat mild and moderate cases of COVID-19 early and prevent spikes in hospitalization that could overwhelm fragile and already overburdened health systems in Africa.

The clinical trial will be carried out at 19 sites in 13 countries by the ANTICOV consortium, which includes 26 prominent African and global research and development (R&D) organizations, coordinated by the Drugs for Neglected Diseases initiative (DNDi), an international non-profit drug research and development (R&D) group with extensive partnerships in Africa.

"There is a need for large clinical trials in Africa for COVID-19 to answer research questions that are specific to an African context," said Dr. John Nkengasong, Director of the Africa Centres for Disease Control and Prevention. "African countries have mounted an impressive response so far to COVID-19 and now is the time to prepare for future waves of the disease. We welcome the ANTICOV trial led by African doctors because it will help answer one of our most pressing questions: With limited intensive care facilities in Africa, can we treat people for COVID-19 earlier and stop our hospitals from being overwhelmed?"

ANTICOV is an open-label, randomized, comparative, 'adaptive platform trial' that will test the safety and efficacy of treatments in 2,000 to 3,000 mild-to-moderate COVID-19 patients in Burkina Faso, Cameroon, Côte d'Ivoire, the Democratic Republic of Congo (DRC), Equatorial Guinea, Ethiopia, Ghana, Guinea, Kenya, Mali, Mozambique, Sudan, and Uganda. ANTICOV aims to identify early treatments that can prevent progression of COVID-19 to severe disease and potentially limit transmission.

"It is heartening to see so many African countries collaborate to get much-needed answers about our unique COVID-19 patient needs," said

Dr. Borna Nyaoke-Anoke, Senior Clinical Project Manager at DNDi, which is also the sponsor for clinical trials in the DRC, Kenya, and Sudan. "Africa has for the most part avoided the large-scale mortality seen in other countries, but with lockdowns ending and borders opening, we need to be prepared. We need research here in Africa that will inform policies and test-and-treat strategies, so that as clinicians we can give the best options to people with COVID-19."

ANTICOV is an adaptive platform trial, an innovative type of clinical trial pioneered for cancer drugs that allows for several treatments to be simultaneously tested. Adaptive platform trials enable rapid decisions to be made, including adding, continuing, or stopping treatment arms based on an ongoing analysis of results.

New treatments will be added to the trial as evidence of their potential for mild-to-moderate cases emerges. ANTICOV researchers are actively looking to select the most promising treatments from ongoing global scientific efforts with proof of efficacy, in collaboration with the Access to COVID-19 Tools Accelerator (ACT-A) Therapeutics Partnership, co-convened by Unitaid and Wellcome on behalf of the COVID-19 Therapeutics Accelerator. Among the potential therapeutic options being explored by ANTICOV are medicines currently used to treat malaria, HIV, hepatitis C, parasitic infections, and certain cancers. The goal is to include additional treatment arms in the ANTICOV trial within weeks.

Initially, ANTICOV will focus on drugs where large-scale randomized clinical trials could provide missing efficacy data in mild-to-moderate patients. The trial will begin testing, against a control arm, the HIV antiretroviral combination lopinavir/ritonavir and the malaria drug hydroxychloroquine, which remains the standard of care for COVID-19 today in numerous African countries.

"The ANTICOV consortium is a broad partnership bringing African

scientific leaders and global R&D organizations together to respond to an urgent unmet medical need. Collaboration is the only way to provide robust scientific responses to these research questions," said Dr. Nathalie Strub-Wourgaft, Director of COVID-19 Response for DNDi. "The trial was designed in a way that enables rapid and flexible decisions as we gather knowledge."

All clinical trial data generated by ANTICOV will be integrated and shared openly and transparently to inform public health policy. Every effort will be made to work with all relevant partners to ensure that treatments that prove safe and effective will be affordable, available, and accessible for all.

The trial was reviewed with support from the African Vaccine Regulatory Forum (AVAREF), a platform established by the World Health Organization (WHO) in 2006, which was recently mandated to expedite clinical trial reviews for COVID-19. Made up of representatives from countries' ethical and regulatory review bodies, AVAREF simplifies and helps accelerate country-level approvals.

ANTICOV is aligned with the WHO R&D Blueprint, which aims to improve coordination between scientists and global health professionals, accelerate the research and development process, and develop new norms and standards to learn from and improve upon the global COVID-19 response.

Provided by Drugs for Neglected Diseases Initiative