DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

513/NDA/DPS/08/2021

20th August 2021

Robert Mijumbi
C/O Ssenkaaba & Co. Advocates,
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Dear Sir,

RE: RESPONSE TO REQUEST FOR AUTHORISATION TO CONDUCT PHASE 1 CLINICAL TRIAL OF COVID-19 CURE CANDIDATE (bertoCOV)

Reference is made to your letter registry no. 5405/21 received on 13th August 2021, regarding your request for permission to conduct a phase 1 trial starting with an oral regimen of the product BertoCOV.

The National Drug Authority (NDA) acknowledges receipt of the following documents and Investigational Medicinal Products samples:

1. Profile of COVID-19 cure candidate and sample labeled D.
2. Profile of HIV cure candidate and sample labeled A
3. Profile of Hepatitis B cure candidate and sample labeled B.
4. Profile of Cancer candidate and sample labeled C.

It was noted that following some findings from in vitro tests you seek to conduct a Phase 1 clinical trial for the Investigational Product **BertoCOV** as a potential treatment for COVID-19 disease.
It was further noted that you intend to conduct clinical studies involving other investigational products namely Berto V1, Berto Hep and Berto CAN for management of Human Immunodeficiency Syndrome(HIV), Hepatitis B and Cancer.

The National Drug Authority authorizes the conduct of Clinical Trials in respect of a drug in line with section 40 of the National Drug Policy and Authority Act. However, the assessment of clinical trial applications for investigational products which are intended for prophylaxis, treatment and diagnosis of COVID -19 are being evaluated in line with the National Guidelines for Conduct of Research during Coronavirus Disease 2019 (COVID-19) pandemic which stipulates that such trials are reviewed through a joint review mechanism coordinated by the Uganda National Council for Science and Technology (UNCST).

The National Drug Authority is inviting you for pre submission meeting scheduled to take place on **Monday 23rd August 2021** at **10.00** am at the NDA head office located on Rumee Towers, Plot 19 Lumumba Avenue.

Below are the requisite documents for submission of a Clinical Trial Application which will form part of the discussion in the meeting above. An application checklist can also be found on our website using the following link https://www.nda.or.ug/application-forms/ ;

1. Clinical Trial Application Form (Form 29 in the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014)

2. The clinical trial protocol for the planned study.
3. Investigator's Brochure for the investigational medicinal product or other Reference Safety Information.
4. Evidence of a favourable opinion of the planned study by an accredited Research Ethics Committee.
5. A copy of the letter of approval and registration with the Uganda National Council for Science and Technology.
6. Participant Information Leaflet and Informed Consent Forms that are approved by the Research Ethics Committee.
7. Certificate of Good Manufacturing Practice for the manufacturer of the investigational herbal medicinal product.
8. Package Inserts for comparator trial medicines.
9. Evidence of accreditation of the designated laboratories where assays will be done (where applicable).
10. Clinical Trials Insurance specific for the clinical trial from a local insurance provider.
11. Signed and completed declarations by all investigators (Form 31 in the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014).
12. Sample of the label for investigational medicinal product as per the requirements of the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014
13. Letter of authorization from the manufacturer or product owner of the investigational medicinal product.
14. Full, legible copies of key, peer-reviewed published articles supporting the clinical trial application.

Thank you for your cooperation.

Sincerely,

David Nahamya,
SECRETARY TO THE AUTHORITY

Copy: Principal Private Secretary to H.E. The President of the Republic of Uganda
The Rt. Hon. Speaker, Parliament of the Republic of Uganda
The Rt. Hon. Prime Minister
The Permanent Secretary, Ministry of Health
The Executive Secretary, Uganda National Council for Science & Technology
The President, Pharmaceutical Society of Uganda
The President, Uganda Medical and Dental Practitioners Council
The Executive Director, Uganda Cancer Institute
The Director General, Uganda AIDS Commission
The Inspector General of Police

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