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FOR IMMEDIATE RELEASE

PRESS RELEASE - FDA APPROVES FIRST HERBAL MEDICINE FOR CLINICAL TRIAL ON COVID-19 TREATMENT

The Food and Drugs Authority (FDA), the National Medicine Regulatory Agency (NMRA) in Ghana, has approved a herbal medicine, *Cryptolepis sanguinolenta*, locally known as Nibima for clinical trials in January 2021.

In search for a treatment for the ongoing COVID-19 pandemic, researchers from the School of Public Health at the Kwame Nkrumah University of Science and Technology, (KNUST), submitted a clinical trial application in September 2020 to assess the safety and efficacy of *Cryptolepis sanguinolenta* as a potential treatment for Covid-19. This follows results from laboratory studies conducted by the KNUST research team which points in the direction of possible clinical benefits.

The FDA Ghana is listed as a WHO "Maturity Level 3" Regulatory Agency, the second country in the WHO African Region to attain this level in the four-tier WHO classification of National Medicines Regulatory Systems. This level, the second within this classification, indicates that Ghana's medicines regulatory system is well functioning and integrates all required elements to guarantee its stable performance, thereby ensuring the safety, quality and efficacy of all medical products imported, exported, manufactured or distributed in the country including the regulation of the conduct of clinical trials.

The FDA after detailed assessment of the application gave the requisite regulatory authorization for the conduct of the trial as per the mandate outlined under Part 8 (Sections 150 - 166) of the Public Health Act 2012 (Act 851), which gives the Authority the legal mandate to regulate clinical trials of drugs, herbal medicinal products, cosmetics or medical devices. The trial will be conducted at two sites.

The research team has over the years been involved in FDA's stakeholder engagements and capacity building activities and has an in-depth experience as well as the knowledge in international and national regulatory requirements requisite for the effective conduct of clinical trials. The sites have adequate capacity to ensure the safety of participants as well as produce credible scientific data.
It is hoped that data from this study may be useful to inform policy or be used for scientific judgments and opinions in relation to COVID-19.

The Authority wishes to assure the general public that it remains committed to protect the health and safety of consumers. To this end, the public is admonished to report any suspicious activity on FDA regulated products to the Authority via any of our platforms:

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FDA…Your Well-being, Our Priority

Signed
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CHIEF EXECUTIVE OFFICER