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COVISTAT, a Subsidiary of Ensysce Biosciences Inc, a California Based Company With a Mission to Solve the Opioid Crisis, Is Commencing Phase 1 Study of Novel COVID-19 Treatment

COVISTAT is launching a phase 1 study after IND approval and promising preclinical findings.

SAN DIEGO--(BUSINESS WIRE)-- COVISTAT Inc. and its parent company Ensysce, received IND allowance and today initiated a Phase 1 clinical trial of oral nafamostat in healthy volunteers. Nafamostat, an ultra-potent protease inhibitor and an ingredient from Ensysce's opioid overdose protection platform, is being developed as an oral treatment for COVID-19. The ultimate goal will be to evaluate if nafamostat mesylate (nafamostat), that has been shown to be an inhibitor of SARS-CoV-2 host cell entry through TMPRSS2, will be effective in preventing progression to acute respiratory failure, to due to COVID-19 infection.

Nafamostat has been approved for intravenous use in Japan for pancreatitis and other diseases, signifying assurance in the drug's safety but has never been approved in the USA. Nafamostat has a novel mechanism of action for treating COVID-19 as a potent protease inhibitor that blocks SARS-CoV-2 viral entry into host cells. Because of this it has antiviral properties against other coronaviruses including the Middle East Respiratory Syndrome (MERS), SARS and now SARS-CoV-2. In addition, nafamostat has anti-inflammatory, anti-coagulant, and mucolytic properties which, in combination, could be vital in helping COVID-19 patients avoid the need for hospitalization.

The Phase 1 trial at the Arizona Research Center in Phoenix, Arizona under the direction of Dr. Joseph Gimbel, is examining nafamostat as an oral solution, a route of administration that has not been studied for this drug. The outcome will be to identify a dose and schedule for a subsequent Phase 2 trial in COVID-19 patients. There is strong interest from other major medical centers in the US, Europe and Asia to conduct Phase 2 trials.

Based on its recently reported studies that demonstrate the potent effect of nafamostat on blocking airway viral entry (https://biorxiv.org/cgi/content/short/2020.09.16.300483v1), COVISTAT also has plans to explore intra-nasal and inhaled routes of administration against COVID-19. Future work will also focus on the viral condition of Multisystem Inflammatory Syndrome in Children (MIS-C). MIS-C in the pediatric population can have extremely serious outcomes in those affected.

Dr. Lynn Kirkpatrick, CEO of Ensysce Biosciences, said, "We are moving very fast and believe a launch may be possible in early 2021. We have previously shown that nafamostat

can be safely administered orally to healthy subjects, and this data allows us to explore the beneficial effects of nafamostat in those individuals who are experiencing symptoms related to COVID-19. Our goal is to deliver a treatment that reduces the need for hospitalization at an affordable cost, in all geographies."

About Ensysce Biosciences, the Opioid Crisis and COVISTAT.
Ensysce Biosciences is developing two new classes of opioid pain products (Trypsin Activated Abuse Protected – TAAP) with overdose protection (MPAR). MPAR uses nafamostat to limit dosing of TAAP products, possibly creating first "overdose proof" opioid. These development programs are being partially funded by the NIH and NIDA, and the first TAAP agent, PF614 has been granted FDA fast-track approval status. The potency of nafamostat to inhibit TMPRSS2 and SARS-CoV-2 viral entry into host cells, prompted Ensysce to establish COVISTAT to explore nafamostat administration alone for COVID-19 therapy.

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