FDA Approves Initiation of IGC's Cannabinoid Trial on Alzheimer's Patients

IGC Announces FDA Removal of Clinical Hold for Multiple Ascending Dose Study of IGC-AD1, Targeting Patients Suffering from Alzheimer's-related Dementia

Potomac, Maryland, August 11, 2020/ BusinessWire / India Globalization Capital ("IGC" or the "Company") (NYSE American: IGC) announced today that on July 30, 2020, the U.S. Food and Drug Administration (FDA) notified IGC that it has authorized the Company to initiate a Phase 1 human trial study for the Company's investigational cannabinoid formulation for the treatment of patients suffering from mild to severe dementia due to Alzheimer's disease. After the completion of administrative tasks, the Company plans to begin enrolling patients suffering from Alzheimer's-related dementia for a 12-subject safety Multiple Ascending Dose (MAD) Study. The Company believes that the FDA's approval of the initiation of the Phase 1 trial is a significant next step in IGC's efforts to develop a potential therapy for treating patients suffering from a devastating disease.

As previously announced, in 2017, the Company acquired exclusive rights to a patent filing by the University of South Florida (USF) entitled "THC as a Potential Therapeutic Agent for Alzheimer's Disease," that uses ultra-low doses of cannabinoids combined with other compounds to create a formulation that is intended to assist in the treatment of Alzheimer's disease. The Company subsequently refiled the patent and filed an additional patent on the formulation that it intended to use as a treatment for Alzheimer's.

In 2018, the Company announced data indicating potential improvement in memory of transgenic mice suffering from Alzheimer's. In 2018, the Company also announced data indicating the formulation's potential efficacy on reducing plaques and tangles in Alzheimer's cell lines. Plaques and tangles are hallmarks of Alzheimer's.

In late 2018, the Company held a pre-Investigational New Drug Application (INDA) submission meeting with the FDA. In 2019, the Company received permission from the Institutional Review Board (IRB) of Puerto Rico to conduct a trial. And, later in 2019, the Company filed an INDA for a 100-person double blind placebo-controlled trial on patients suffering from Alzheimer's disease.

According to the Alzheimer's institute about 5.5 million individuals suffer from Alzheimer's in the United States and about 44 million suffer from the disease worldwide. Currently, there is no cure for Alzheimer's disease.

"Our strategy with IGC-AD1 is to initially conduct trials that establish the efficacy of IGC-AD1 on the Behavioral and Psychological Symptoms of Dementia (BPSD). Patients with moderate Alzheimer's suffer from BPSD that includes among other symptoms delusions, agitation, aggression, depression, anxiety, apathy, and sleep disorder. Eventually, we expect to evaluate the efficacy of IGC-AD1 on plaques and tangles, the hallmarks of Alzheimer's disease. We are excited with the progress made and that the FDA will allow the Company to initiate trial testing on human subjects using natural organic cannabis extracts. We believe that this a first human trail of this sort," said Ram Mukunda, CEO of IGC.

Forward-looking Statements:
This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are based largely on IGC's expectations and are subject to a number of risks and uncertainties, certain of which are beyond IGC's control. Actual results could differ materially from these forward-looking statements as a result of, among other factors, worsening of the COVID-19 outbreak in China, the U.S., and other parts of the world, the prolonged continuation of travel restrictions related to the outbreak, continued disruption of the Hong Kong economy, competitive conditions in the industries in which IGC operates, failure to meet operational goals and/or revenue and profit targets for products in various stages of production and commercialization, failure to commercialize one or more of the products or technologies of IGC, including any products or patented formulations identified herein, or the failure or inability to pay patent maintenance fees, unexpected trial results or trial results that do not support the efficacy of our formulation, potential rejection of any patent application even when the Company is in compliance with USPTO requirements, any changes in federal, state, or local law applicable to our businesses and the locations where we operate, general economic, political, and health and welfare conditions that are less favorable than expected, the FDA's general position regarding hemp-based and related products in particular, the FDA's decision to deny approval of further trials, or investigative new drug application, and other factors, many of which are discussed in our SEC filings. Precautions including social distancing, travel restrictions, among others, surrounding the Covid-19 pandemic could lead to delays and a more expensive trial. The Risk Factors identified in the Company's annual report, filed on Form 10-K with the SEC on July 13, 2020, and in the Company's quarterly reports, filed on Form 10-Q with the SEC on November 5, 2019 and February 10, 2020, are incorporated herein by reference. In light of these risks and uncertainties, there can be no assurance that the forward-looking information contained in this release will in fact occur.

About IGC:
IGC has two lines of business: infrastructure and life sciences, including hemp-derived medical cannabis/industrial hemp. The company is based in Maryland, U.S.A. Our website: www.igcpharma.com, www.igcinc.us. Twitter @IGCIR

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