



IGCPHARMA

IGC Pharma Expands Phase 2 Trial of IGC-AD1 to Include the University of Puerto Rico

- First patient dosing commenced on May 19, 2023
- Trial enrollment completion and top line data expected in early 2024

POTOMAC, Md., August 02, 2023 - IGC Pharma, Inc (NYSE American: IGC) (“IGC” or the “Company”), today announced the addition of an important trial site at the University of Puerto Rico network as an expansion of the Company’s ongoing Phase 2 clinical trial investigating lead drug asset, IGC-AD1, as a treatment for lowering agitation in patients with Alzheimer’s disease.

According to clinicaltrials.gov, IGC-AD1 is the only natural THC-based investigational drug undergoing FDA trials. The therapy relies on low doses of THC and another compound as pharmaceutical active agents for the treatment of Alzheimer’s disease and has shown in pre-clinical studies the potential to be effective in ameliorating A β plaques and in Phase 1 the potential to reduce neuropsychiatric symptoms such as agitation in dementia due to Alzheimer’s.

The expansion of the Phase 2 trial into Puerto Rico aims to increase population diversity and promote the inclusion of underrepresented populations. The Company plans to further increase population diversity by adding future sites in South America and Canada. The trial will enroll 146 patients with one half, the treated group, receiving IGC-AD1, and the other half, the control group, receiving a placebo. The goal of the trial is to evaluate and establish the efficacy of IGC-AD1 in helping patients with Alzheimer’s dementia reduce neuropsychiatric symptoms (“NPS”) such as agitation, which affects 76% of individuals with Alzheimer’s (*Mussele et al., 2015*).

Dr. Vanessa Sepúlveda-Rivera, Principal Investigator for the University of Puerto Rico trial sites commented, *“Up to 12.5% of the ageing population of Puerto Rico has Alzheimer’s Disease, which is an increase from 10.7% reported for the continental U.S. population. It is vital that medical research include Hispanic populations in order to yield the most reliable data resulting in the most effective therapies. We look forward to moving ahead with the study and investigating this THC-based technology.”*

“We are excited to announce our partnership with the University of Puerto Rico, a remarkable institution conducting world-leading medical research. The addition of this site with individuals living with Alzheimer’s from the Hispanic community is a significant milestone in our Phase 2 trial. Alzheimer’s disease, including the resulting symptom of agitation, is complex to treat and incredibly hard to live with”, commented Ram Mukunda, Chief Executive Officer of IGC Pharma, Inc.

About IGC Pharma, Inc.

IGC Pharma, Inc. (dba IGC) develops advanced cannabinoid-based formulations for treating diseases and conditions, including, but not limited to, Alzheimer’s disease, period cramps (“dysmenorrhea”), premenstrual syndrome (“PMS”) and chronic pain. IGC has two investigational drug assets targeting Alzheimer’s disease, IGC-AD1 and TGR-63, which have demonstrated in Alzheimer’s cell lines the potential to be effective in suppressing or ameliorating key hallmarks of Alzheimer’s disease, such as plaques or tangles. IGC-AD1 is a low-dose tetrahydrocannabinol (“THC”) based formulation that is currently in a 146-person Phase 2 clinical trial for agitation in dementia due to Alzheimer’s (<https://clinicaltrials.gov/ct2/show/NCT05543681>). IGC also markets a wellness brand, Holief™, that targets women experiencing premenstrual syndrome and menstrual cramps.

Forward-looking Statements

This press release contains forward-looking statements. These forward-looking statements are based largely on IGC's expectations and are subject to several 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, the Company's failure or inability to commercialize one or more of the Company's products or technologies, including the products or formulations described in this release, or failure to obtain regulatory approval for the products or formulations, where required; general economic conditions that are less favorable than expected, including as a result of the ongoing COVID-19 pandemic; the FDA's general position regarding cannabis- and hemp-based products; and other factors, many of which are discussed in IGC's U.S. Securities and Exchange Commission ("SEC") filings. IGC incorporates by reference the human trial disclosures and Risk Factors identified in its Annual Report on Form 10-K filed with the SEC on July 7, 2023, as if fully incorporated and restated herein. In light of these risks and uncertainties, there can be no assurance that the forward-looking information contained in this release will occur.

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