



## **IGC Commences Phase 2 Clinical Trials Evaluating Drug Candidate IGC-AD1 for the Treatment of Agitation in Dementia From Alzheimer’s Disease**

Company To Host Conference Call on Friday, December 2 at 11 a.m. ET

POTOMAC, MD., December 01, 2022-- (Business Wire) -- India Globalization Capital, Inc. (NYSE American: IGC) (“IGC” or the “Company”), announced that it has begun “A Phase 2, Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Trial of the Safety and Efficacy of IGC-AD1 on Agitation in Participants with Dementia due to Alzheimer’s Disease”.

The Company has commenced the Phase 2 study at two U.S. sites with plans to add between three to five additional sites in the United States, Canada, and possibly South America to increase population diversity, promoting both the inclusion of underrepresented populations and helping the Company to better understand the impact of IGC-AD1 on the population of the Americas. 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). Currently, there is no Food and Drug Administration (“FDA”) approved drug for treating agitation in dementia related to Alzheimer’s (Jones et al., 2021).

“We believe that IGC-AD1 has the potential to revolutionize the treatment of Alzheimer’s Disease as the first and only low-dose natural THC-based formulation candidate currently undergoing FDA trials,” commented Ram Mukunda, CEO of IGC. “Approximately 8 million people are affected by Alzheimer’s in North America and over 55 million worldwide. We believe the diverse population we have selected for this study will allow us to accurately look at both the impact of variations of the gene CYP2C9 that metabolizes THC, as well as APOE e4 a gene that increases the risk of developing Alzheimer’s. This data will help us to further understand the metabolism of IGC-AD1 for a diverse population, which is important in treating a disease that has a global impact like Alzheimer’s. Through these and further trials, we look forward to establishing IGC-AD1’s efficacy in treating the symptoms related to Alzheimer’s Disease.”

IGC-AD1 relies on low-doses of THC, a psychoactive cannabinoid, and another compound as active agents in trials for Alzheimer’s. The formulation has recently completed Phase 1 of clinical trials required by the FDA and demonstrated in Alzheimer’s cell lines the potential to be effective in suppressing or ameliorating a key protein that is responsible for A $\beta$  plaques; a key hallmark of the disease.

For further information, please visit <https://clinicaltrials.gov/ct2/results?cond=&term=IGC-AD1&cntry=&state=&city=&dist=>

### Conference Call Details

Management will host a conference call and webcast with an accompanying slide presentation on Friday, December 2, 2022, at 11:00 a.m. ET.

Interested investors may participate via the webcast using the following link:

<https://www.webcaster4.com/Webcast/Page/2938/47255>

To participate via conference call, please use the following **dial-in numbers and use access code 638516** when prompted by the operator.

- (888) 506-0062 (Domestic)
- (973) 528-0011 (International)

A replay of the call will also be available at the above link.

## **About IGC**

India Globalization Capital Inc. develops advanced cannabinoid-based formulations for treating diseases, including but not limited to Alzheimer's disease, Parkinson's disease, chronic pain, and pet seizures. The Company's leading drug candidate, IGC-AD1, has demonstrated, in Alzheimer's cell lines, the potential to be effective in suppressing or ameliorating a key protein responsible for A $\beta$  plaques and has recently entered Phase 2 clinical trials for agitation in dementia from Alzheimer's. The Company also has lines of various CBD-based consumer products such as Holief, which includes gummies and pain relief creams for women experiencing premenstrual syndrome ("PMS") and dysmenorrhea ("period cramps"), and Sunday Seltzer, which includes a CBD-infused energy beverage – all currently available for purchase. The Company operates facilities in the US under GMP certification (*Good Manufacturing Practices*). The Company also operates an Infrastructure business based in India. The Company is headquartered in Maryland, U.S.A.

## **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 favourable 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 June 23, 2022, 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.

## **Contact:**

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