BioHarvest Sciences Announces Clinical Study in Patients with Multiple Sclerosis-Related Optic Neuritis

- Study will assess the Capacity of its Red Grape Cell (RGC) Botanical Composition to Promote Eye Health
- Study is first to demonstrate potential capabilities of BioHarvest's Botanical-Synthesis technology to provide consistent APIs, adjuvants and drugs for pharmaceutical industry

Vancouver, British Columbia, and Rehovot, Israel--(Newsfile Corp. - February 14, 2023) - BioHarvest Sciences Inc. (CSE: BHSC) (OTCQB: CNVCF) ("BioHarvest" or the "Company") has announced a collaboration with the International Neurorehabilitation Institute (INI) (<u>https://inirehab.com/</u>) in Lutherville, Maryland to perform a clinical trial to assess the capacity of its RGC composition to promote eye health.

The study will be led by Dr. Daniel Becker, Director of the INI and Assistant Professor of Neurology at Johns Hopkins School of Medicine. RGC is a patented composition based on BioHarvest's Botanical-Synthesis technology, with consistency and quality that have potential to meet the criteria for being used as an Active Pharmaceutical Ingredient (API).

The planned translational open-label clinical study will evaluate the impact of RGC on multiple sclerosis (MS)-related optic neuritis driven by inflammation. The study – the latest of several human clinical trials run by BioHarvest – aims to elucidate the mechanisms through which RGC impacts the disease by measuring anti-oxidative, detoxifying, and inflammatory biomarkers.

"To date there are no medications that can help improve vision after an acute optic neuritis event. This exciting research will help us understand if phytonutrients are capable of affecting the inflammatory environment as well as the neuro-regenerative capacity within the injured central nervous system," said Dr Daniel Becker, who is the study's lead investigator.

The research team hypothesizes that RGC will result in positive changes to eye health by modulating a variety of biomarkers compared to baseline in the study participants.

The next important step for this study is submission to an Institutional Review Board (IRB) to be followed by the study launch with 15-30 participants.

"This is the first human clinical study to evaluate the combination of health-promoting phytonutrients as found in RGC for the promotion of eye health," said BioHarvest Chief Medical Officer Dr. Brian Cornblatt, co-investigator of the study.

"Many patients with MS suffer with optic neuritis and to date the standard of care includes in-patient high-dose steroids," Dr. Comblatt added. "Considering many people with MS take biologics which have immunosuppressing properties, adding high-dose steroids is not ideal in the current environment, with a pandemic and influenza on the rise globally. We need to go back to medicine's roots, literally, and study safe, effective, and affordable phytonutrients derived from plants."

"What's exciting is that we knowthat phytonutrients in RGC help modulate key molecular pathways at the cellular level, including up-regulating anti-oxidative enzymes. We viewthis study as a first step to validate this concept. It will be followed by a longer-term plan to assess the effectiveness of RGC in restoring different aspects of eye health. A larger, multi-center, controlled clinical trial aiming at bridging eye health support with changes in validated biomarkers will help confirm the protective role of phytonutrients," said Dr. George Garibaldi, member of the Scientific Advisory Board of BioHarvest.

The Multiple Sclerosis Foundation estimates more than 1 million people in the United States and about 2.5 million people worldwide have been diagnosed with MS, and some 200 new cases are diagnosed weekly in the US alone. While the root causes of MS are still unknown, there are definite links between genetic and select environmental factors.

"We are inspired by nature and driven by science. Clinical studies are an important pillar in building a company that creates products that are both trusted and effective for our customers," said BioHarvest CEO llan Sobel. "As a biotech company dedicated to health and wellness, we plan to extend our Botanical-Synthesis technology into the pharmaceutical industry. This collaboration with such a reputable North American research partner marks an important step to create additional science-based therapeutic solutions that provide better treatment options."

About BioHarvest Sciences Inc.

BioHarvest Sciences Inc. (CSE: BHSC) is a fast-growing Biotech firm listed on the Canadian Securities Exchange. BioHarvest has developed a patented bio-cell growth platform technology capable of growing the active and beneficial ingredients in fruit and plants, at industrial scale, without the need to grow the plant itself. This technology is economical, ensures consistency, and avoids the negative environmental impacts associated with traditional agriculture. BioHarvest is currently focused on nutraceuticals and the medicinal cannabis markets. Visit: www.bioharvest.com.

BioHarvest Sciences Inc.

llan Sobel, Chief Executive Officer

For further information, please contact:

Dave Ryan, VP Investor Relations & Director Phone: 1 (604) 622 -1186 Email: <u>dave@bioharvest.com</u>

Facebook Twitter LinkedIn YouTube

Forward-Looking Statements

Information set forth in this news release might include forward-looking statements that are based on management's current estimates, beliefs, intentions, and expectations, and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. There is no assurance that the Company will be successful in expanding its technology to broader medical applications or conduct clinical trials to validate the efficacy of the Company's products for newforms of medical treatments. Clinical trials are subject to risks of significant cost overruns and lengthy delays with no assurance they will confirm desired results. Even where desired results are obtained, government approvals for treatments take considerable time and cannot be guaranteed. There is no assurance that the company will develop therapies addressing health conditions which could take considerable time and require resources and clinical trials beyond the capacity of the Company.

All forward-looking statements are inherently uncertain and actual results may be affected by a number of material factors beyond our control. Readers should not place undue reliance on forward-looking statements. BHSC does not intend to update forward-looking statement disclosures other than through our regular management discussion and analysis disclosures.

Neither the Canadian Securities Exchange nor its Regulation Services Provider accept responsibility for the adequacy or accuracy of this release.



To view the source version of this press release, please visit <u>https://www.newsfilecorp.com/release/154686</u>