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Lexaria's DehydraTECH-CBD Hypertension Study HYPER-H21-4 Dosing Complete with No Serious Adverse Events

KELOWNA, BC / ACCESSWIRE / July 27, 2022 /Lexaria Bioscience Corp.

(NASDAQ:LEXX)(NASDAQ:LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms is pleased to announce that dosing with Lexaria's DehydraTECH™-processed cannabidiol ("DehydraTECH-CBD") has been completed in its multi-week human clinical hypertension study HYPER-H21-4, and that no serious adverse events have been reported as a result of the dosing.

HYPER-H21-4, is a randomized, double blinded, placebo-controlled, cross-over study that was designed to enrol a minimum of 60 patients. Dosing has now completed, meaning all patients at different times during the study have now received both the full DehydraTECH-CBD dose regimen as well as the placebo. A total of 64 patients were dosed in this study. Maximum dose levels were roughly 5 mg/kg/day which is significantly lower than maximum dose levels practiced for other regulator-approved pharmaceutical CBD applications, which Lexaria postulates may be beneficial in avoiding unwanted side effects such as clinically significant elevated liver enzymes sometimes reported in the published scientific literature at higher dose levels.

"We are extremely pleased that dosing has been completed on time in this multi-week clinical study without any serious adverse events having occurred," said Chris Bunka, CEO of Lexaria Bioscience Corp. "Demonstrating a noteworthy safety and tolerability profile relative to conventional anti-hypertensive medications is one of Lexaria's major goals with this program, and avoiding serious adverse events at clinically efficacious doses will be a primary requirement to achieve eventual regulatory marketing authorizations."

HYPER-H21-4 is designed to enhance Lexaria's probability of success toward an Investigational New Drug ("IND") application filing to seek U.S. Food and Drug Administration ("FDA") approval to commence registered clinical testing at the Phase I level or higher, to be determined in consultation with the FDA. This human study is also expected to enhance Lexaria's understanding of DehydraTECH-CBD for the treatment of cardiovascular and other disease states beyond hypertension related to increased arterial stiffness and blood biochemistry, pursuant to earlier promising findings in this area. HYPER-H21-4 follows Lexaria's previously announced successes in significantly reducing blood pressure in similarly hypertensive human volunteers in its 2021 studies [HYPER-H21-1](#) and [HYPER-H21-2](#).

HYPER-H21-4 consisted of male and female volunteers between the ages of 40-70 with

documented or measured elevated blood pressure (120/80 to 139/80 mmHg), mild (stage 1) hypertension (140/90 to 159/99 mmHg) or moderate (stage 2) hypertension (160/100 to 179/109 mmHg) who received DehydraTECH-CBD every day for a 5-week duration. DehydraTECH-CBD doses escalated between 225 mg/day to 450 mg/day over the study duration adjusted relative to body weight. Some volunteers were already using leading standard of care hypertension drugs such as angiotensin-converting enzyme ("ACE") inhibitors with or without diuretics and/or calcium channel blockers, which will help evaluate the safety and efficacy of DehydraTECH-CBD with and without other hypertension treatments. The extended duration of the study allowed Lexaria to gather critical data monitoring the safety and efficacy of DehydraTECH-CBD over time and will evaluate the potential for longer term health benefits.

HYPER-H21-4 is more comprehensive than any clinical study previously undertaken by Lexaria and many types of analysis will be performed including 24-hour ambulatory blood pressure, which is the primary study outcome.

Secondary study outcomes include: vascular health including arterial stiffness and autonomic balance; electrocardiogram ("ECG") analysis; brain structure and function through MRI testing; blood biomarkers (including renal, hepatic inflammation, lipids such as cholesterol and more); sleep quality / daytime sleepiness / sleep disorders; actigraphy, geriatric depression scale, perceived stress, and Beck anxiety inventory. Large quantities of data have been gathered since the initiation of the study, and most data analyses will begin in September once results are available from ongoing bioanalyses work upon biological samples collected during the study.

Each of these sets of data may lead to additional applications for DehydraTECH-CBD. For example, the MRI data may assist one of the secondary outcome measurements in the study to evaluate possible positive effects upon brain structure and function; and the detailed psychometric testing may reveal new insights into the potential benefits for mental health. The wide range of data collection could provide additional insights into the long-term health benefits of DehydraTECH-CBD that might otherwise remain undetected.

About Lexaria Bioscience Corp.

Lexaria Bioscience Corp.'s patented drug delivery technology, DehydraTECH™, improves the way active pharmaceutical ingredients (APIs) enter the bloodstream by promoting more effective oral delivery. Since 2016, DehydraTECH has repeatedly demonstrated the ability to increase bio-absorption with cannabinoids, antiviral drugs, PDE5 inhibitors and more. DehydraTECH has also evidenced an ability to deliver some drugs more effectively across the blood brain barrier. Lexaria operates a licensed in-house research laboratory and holds a robust intellectual property portfolio with 25 patents granted, 1 patent allowed, and roughly 50 patents pending worldwide. For more information, please visit www.lexariabioscience.com.

CAUTION REGARDING FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. Statements as such term is defined under applicable securities laws. These statements may be identified by words such as "anticipate," "if," "believe," "plan," "estimate," "expect," "intend," "may," "could," "should," "will," and other similar expressions. Such forward-looking statements in this press release

include, but are not limited to, statements by the company relating the Company's ability to carry out research initiatives, receive regulatory approvals or grants or experience positive effects or results from any research or study. Such forward-looking statements are estimates reflecting the Company's best judgment based upon current information and involve a number of risks and uncertainties, and there can be no assurance that the Company will actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements. As such, you should not place undue reliance on these forward-looking statements. Factors which could cause actual results to differ materially from those estimated by the Company include, but are not limited to, government regulation and regulatory approvals, managing and maintaining growth, the effect of adverse publicity, litigation, competition, scientific discovery, the patent application and approval process, potential adverse effects arising from the testing or use of products utilizing the DehydraTECH technology, the Company's ability to maintain existing collaborations and realize the benefits thereof, delays or cancellations of planned R&D that could occur related to pandemics or for other reasons, and other factors which may be identified from time to time in the Company's public announcements and periodic filings with the US Securities and Exchange Commission on EDGAR. There is no assurance that any of Lexaria's postulated uses, benefits, or advantages for the patented and patent-pending technology will in fact be realized in any manner or in any part. No statement herein has been evaluated by the Food and Drug Administration (FDA). Lexaria-associated products are not intended to diagnose, treat, cure or prevent any disease. Any forward-looking statements contained in this release speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

INVESTOR CONTACT:

George Jurcic - Head of Investor Relations

ir@lexariabioscience.com

Phone: 250-765-6424, ext 202

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