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Lexaria Commences Multi-Week Human Clinical Hypertension Study

- ***HYPER-H21-4 will evaluate DehydraTECH™-CBD for reducing blood pressure together with other potential clinical benefits***
- ***This study is designed to enhance Lexaria's probabilities of success with its expected subsequent Investigational New Drug application filing***

KELOWNA, BC / ACCESSWIRE / April 19, 2022 Lexaria Bioscience Corp. (NASDAQ:LEXX) (NASDAQ:LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms, is pleased to announce that it has begun its multi-week human clinical hypertension study.

The study, HYPER-H21-4, is a randomized, double blinded, placebo-controlled, cross-over study in 60 people and the most comprehensive study ever undertaken by Lexaria. Dosing in more than half the volunteers has already commenced ahead of schedule, with all treatment visits expected to conclude in early July, 2022. Baseline brain magnetic resonance imaging ("MRI") scanning has also already begun. Of significant note, there have been no serious adverse events reported by these volunteers, demonstrating that DehydraTECH-CBD has been well tolerated in those that have received it thus far.

HYPER-H21-4 is designed to enhance Lexaria's probability of success with its expected subsequent Investigational New Drug ("IND") application filing to seek 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, 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](#).

This study is entirely funded through the Company's existing cash resources and is not subject to any financing requirement. Independent Review Board approval was received in December 2021. The clinical test articles for this study have been manufactured, quality control tested and shipped to the European research hospital conducting the study.

HYPER-H21-4 consists of a minimum of 60 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 will use DehydraTECH-CBD every day for a 5-week duration. DehydraTECH-CBD doses will escalate between a range of 225 mg/day to 450 mg/day over

the study duration. Some volunteers will already be 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 efficacy of DehydraTECH-CBD with and without other hypertension treatments. The extended duration of the study will allow 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 work 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 lipids such as cholesterol and more); renal and hepatic analysis, sleep quality / daytime sleepiness / sleep disorders; actigraphy, geriatric depression scale, perceived stress, and Beck anxiety inventory. 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.

Lexaria will provide further updates on the progress of study HYPER-H21-4 and its IND application enabling program as they become available. Details on the outcomes after the expected July conclusion of all treatment visits in study HYPER-H21-4 will follow in due course after performing the necessary data analyses.

Hypertension Markets

The hypertension market is valued at [\\$28 billion per year](#) and is expected to continue growing as one of the world's top health problems and as a subset of the larger heart disease market. Geographically, some of the highest rates of growth are expected in more recently industrialized nations such as China and India. [Over 1.1 billion people](#) worldwide suffer from hypertension.

Fewer than [1 person in 4 with hypertension](#) have successfully controlled their blood pressure through medications, meaning the potential market for hypertension drugs is much larger than \$28 billion per year if an affordable drug was available with few or no side effects. Lexaria believes that its DehydraTECH-CBD may introduce a more tolerable anti-hypertensive treatment option that may be used alone or in combination with other medications, to reduce BP with fewer discouraging and unwanted side effects. Lexaria would seek to satisfy this currently unmet demand and in doing so could expand the overall hypertension market.

"Among persons 50 years of age or older, isolated systolic hypertension is the most common form of hypertension, and systolic blood pressure becomes more important than diastolic blood pressure as an independent risk predictor for coronary events, stroke, heart failure, and end-stage renal disease (ESRD). The Global Burden of Disease Study identified elevated blood pressure as the leading risk factor, among 67 studied, for death and

disability-adjusted [life-years lost during 2010](#)."

Drugs focused on blood pressure and related conditions are some of the [highest selling drugs](#) in the world. Lipitor, used to treat high cholesterol and reduce the risk of heart disease, has generated \$94.7 billion in revenue from 1992 until 2017. Plavix, used to prevent heart attack and stroke, has sold \$46.5 billion from 1992 until 2017. There are [several hypertension drugs](#) that each generate \$1 billion per year or more in revenue.

About DehydraTECH-CBD

DehydraTECH-CBD is a unique CBD formulation Lexaria has developed and is optimizing based on its patented and proprietary DehydraTECH drug delivery technology. DehydraTECH is designed to improve the way active molecules enter the bloodstream upon oral ingestion. DehydraTECH has also demonstrated enhanced delivery of certain active molecules including CBD into brain tissue, which Lexaria believes to be of particular importance for the effectiveness of its DehydraTECH-CBD specifically against hypertension because of the significant influence of central mediation upon blood pressure. Lexaria has also developed DehydraTECH-CBD formulations for other applications demonstrating superior bioabsorption when administered intraorally and topically.

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 and nicotine by up to 5-10x, reduce time of onset from 1 - 2 hours to minutes, and mask unwanted tastes; and is also being evaluated for orally administered anti-viral drugs, non-steroidal anti-inflammatory drugs (NSAIDs), 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 24 patents granted and over 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.

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