

# Lexaria Receives Independent Review Board Approval For DehydraTECH-CBD Human Clinical Study HYPER-H21-4

Dosing is expected to begin by April, 2022

**KELOWNA, BC / ACCESSWIRE / December 29, 2021 /**Lexaria Bioscience Corp. (NASDAQ:LEXX)(NASDAQ:LEXXW) (the "**Company**" or "**Lexaria**"), a global innovator in drug delivery platforms, is pleased to report that Independent Review Board ("IRB") approval has been received ahead of schedule for its upcoming DehydraTECH-CBD human hypertension study HYPER-H21-4.

This study should "de-risk" outcomes prior to Lexaria's planned entry into regulatory pathways for the use of DehydraTECH-CBD to treat hypertension and perhaps other forms of cardiovascular disease. This study is entirely funded through the Company's existing cash resources and is not subject to any financing requirement. Dosing is tentatively scheduled to begin by April, 2022.

HYPER-H21-4 is expected to consist of 60 volunteers between the ages of 45-70 using three 150 mg doses of DehydraTECH-CBD, every day for the 6-week duration of the study. The study will use a double blinded, randomized cross-over design, and a placebo control. Some volunteers will already be using leading standard of care hypertension drugs such as ACE inhibitors with or without diuretics 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 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 (the primary outcome); arterial stiffness and autonomic balance; brain structure and function through brain magnetic resonance imaging ("MRI"); blood biomarkers (including lipids such as cholesterol and more); renal, hepatic, sleep quality / daytime sleepiness / sleep disorders; actigraphy, geriatric depression scale, perceived stress, and Beck anxiety inventory. The wide range of data collection could provide additional insights into the long-term health benefits of DehydraTECH-CBD that might otherwise remain undetected.

## **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. <u>Over 1.1 billion people</u> 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 antihypertensive 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 <a href="https://drugs.ni.nlm.ni.go/high-en/">https://drugs.ni.nlm.ni.go/high-en/</a> 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 <a href="mailto:several-hypertension drugs">several-hypertension drugs</a> that each generate \$1 billion per year or more in revenue.

# **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 5-10x and, in some instances with cannabinoids by as much as 27x compared to standard industry formulations, 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), 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 inhouse research laboratory and holds a robust intellectual property portfolio with 23 patents granted and over 50 patents pending worldwide. For more information, please visit <a href="https://www.lexariabioscience.com">www.lexariabioscience.com</a>.

### 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** 

<u>ir@lexariabioscience.com</u>

Phone: 250-765-6424, ext 202

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