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# Lexaria Announces Ambitious New Hypertension Study HYPER-H21-4

- *DehydraTECH-CBD also being evaluated in three other human clinical studies*
- *Positive studies would support Lexaria's regulatory approval plans*

**KELOWNA, BC / ACCESSWIRE / November 3, 2021** / Lexaria Bioscience Corp. (NASDAQ:LEXX)(NASDAQ:LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms, announces a significant new study to expand its hypertension clinical program and provides updates on three ongoing human clinical studies evaluating its proprietary DehydraTECH-CBD for potentially treating hypertension and heart disease.

"HYPER-H21-4 is the most ambitious study Lexaria has ever undertaken and is enabled from the successful outcomes from our other 2021 human hypertension studies," said Chris Bunka, CEO of Lexaria Bioscience Corp. "Outcomes from this study could support Lexaria's goals related to pursuit of regulatory approvals for DehydraTECH-CBD for potential use as a treatment for high blood pressure."

## **HYPER-H21-4**

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 utilize a placebo control. Some volunteers will already be using leading standard of care hypertension drugs such as ACE inhibitors with or without diuretics to 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 extended use of DehydraTECH-CBD and will evaluate the potential for longer term health benefits. Study protocols are being readied for submission to the Independent Review Board ("IRB") and approval is anticipated by January, 2022.

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 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 benefits of DehydraTECH-CBD that might otherwise remain hidden from view.

HYPER-H21-4 is expected to produce an enormous amount of data that, if positive, should

be supportive of Lexaria's plans to enter regulatory pathways anticipated to result in eventual regulatory approval to use 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.

## **Updates on Other Hypertension Studies**

### **HYPER-H21-1**

Partial results, related only to BP readings, were [released](#) on July 29, 2021, as summarized below. This study was conducted in 24 adult volunteers, used a single dose of 300 mg of DehydraTECH-CBD, and measured results over a number of hours. Pending analyses and results include speed and rate of absorption of the CBD and its main metabolites, as well as evaluation of inflammatory markers associated with cardiovascular disease and gold-standard biomarkers of nitric oxide. This latter measure is expected to provide mechanistic insight into the witnessed reduction in blood pressure via vasodilation. Those results were originally expected to be released by October, but are now due by early December due to certain supply chain challenges.

BP reduction from baseline was greatest when measured via systolic pressure. In the subset of volunteers who were Stage 2 hypertensive, peak systolic BP reductions from baseline were observed of as much as approximately 13 mmHg by the 50-minute time point with DehydraTECH-CBD, and systolic BP remained depressed throughout almost the entire 3-hour duration of the study. For reference, [other studies](#) of coronary heart disease ("CHD") have concluded that "*lowering [systolic pressure](#) by 10 mm Hg or diastolic pressure by 5 mm Hg using any of the main classes of drugs reduced CHD events (fatal and nonfatal) by about a quarter and stroke by about a third, regardless of the presence or absence of vascular disease and of pretreatment BP. Heart failure is also reduced by about 25%.*"

### **HYPER-H21-2**

Partial results were [released](#) on September 7, 2021 as summarized below. This study was conducted in 16 adult volunteers, used three doses of 150 mg each of DehydraTECH-CBD, and measured results over a 24-hour ambulatory time-period. Pending analyses and results to be concluded include additional blood pressure subset analyses, sleep quality and other data analyses that are in progress and final results are expected in early December.

At selected times during the 24-hour study, volunteers with mild to moderate hypertension averaged as much as a 20 mmHg (i.e., 23%) decrease in BP relative to placebo. Over the 24-hour ambulatory monitoring period, volunteers averaged a significant reduction of 7.0% ( $p < 0.001$ ) in systolic pressure with DehydraTECH-CBD relative to placebo.

### **HYPER-H21-3**

DehydraTECH-CBD manufacturing for this study is complete and the clinical test articles have been delivered to the study location where dosing is expected to begin in mid-November or thereabouts, and dosing is expected to be complete by mid-December. Thereafter, the BP findings are expected to be reportable by the end of January, 2022.

HYPER-H21-3 will be conducted in 16 adult volunteers and will utilize a single dose of

300mg of DehydraTECH-CBD. This study is designed to evaluate acute pulmonary hypertension and cardiovascular effects under severe stress. Exposure to acute reductions in oxygen tension (i.e., hypoxia) causes rapid hypoxic pulmonary vasoconstriction ("HPV") and, as a consequence of this HPV response, pulmonary arterial pressure increases. If this increase in pressure becomes too high, as is the case in many cardiac pathologies, an excess of fluid in the lungs can occur that causes difficulty with breathing. The extent to which DehydraTECH-CBD may act as a novel treatment for HPV, and potentially as an alternative treatment for pulmonary hypertension, is unknown. Thus, the primary objective of this study is to evaluate the effect of DehydraTECH-CBD on pulmonary vascular function in normotensive individuals exposed to hypoxia. The magnitude of HPV, blood pressure, heart rate, blood samples, and pulmonary gas exchange data will be collected and analyzed.

## **Hypertension and Cardiovascular Disease Markets**

[About 1.28 billion people](#) worldwide suffer from hypertension - elevated blood pressure-in a market valued at [\\$28 billion per year](#) and is recognized as one of the world's top health problems. Only 21% of people with hypertension have it under control which demonstrates enormous unmet need. Hypertension is one subset of the broader cardiovascular disease category, which is expected to be a [\\$146 billion market in 2022](#).

"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 [best 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 is 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 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 23 patents granted and over 50 patents pending worldwide. For more information, please visit [www.lexariabioscience.com](http://www.lexariabioscience.com).

## **CAUTIONARY NOTE 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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