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# Lexaria Expands R&D Program to Address US\$28 Billion Hypertension Market with Addition of Two Human Clinical Studies

- *Hypertension program evaluating effectiveness of DehydraTECH-processed CBD now consists of three human clinical studies and two animal studies*

**KELOWNA, BC / ACCESSWIRE /February 11, 2021 /**Lexaria Bioscience Corp. (NASDAQ:LEXX)(NASDAQ:LEXXW)(CSE:LXX) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms, announces significant progress in its 2021 applied research and development (R&D) program with additional focus on hypertension.

"Over 1.1 billion people suffer from hypertension," said Chris Bunka, CEO of Lexaria. "Pending successful completion of Lexaria's study programs, we intend to pursue opportunities for growth through strategic partnerships with leading companies active in the hypertension drug or CBD pharmaceutical marketplaces."

## **DehydraTECH-CBD For Hypertension**

The overall 2021 Lexaria hypertension program now consists of a total of five studies, three of which were described in the Company's announcement on February 1, 2021 and updated here (HYPER-A21-1, HYPER-A21-2, and HYPER-H21-1), and two new additions, which are announced now for the first time (HYPER-H21-2 and HYPER-H21-3).

Study design for the Company's planned animal studies HYPER-A21-1 and HYPER-A21-2 has been completed, and delivery of the formulations to be tested to the third-party laboratories in good condition has been confirmed. Dosing remains on schedule, and is expected to begin in late February or early March.

HYPER-H21-1 as previously announced, and the new additions, HYPER-H21-2 and HYPER-H21-3, are each randomized, double-blinded human clinical studies to take place in Europe. Study design for HYPER-H21-1 is complete and university hospital and ethics board approvals have been received. Subject dosing for HYPER-H21-1 will begin after shipment of the clinical test articles to the clinical site is completed, pending regulatory clearances for importation as previously announced.

HYPER-H21-2 has been added to the Lexaria hypertension program due to the increasing importance that this work could have on Lexaria's commercial prospects. This study is designed to monitor ambulatory blood pressure during a 24-hour period after subject dosing, with subjects wearing portable devices that will record blood pressure at 30-minute and 60-minute intervals. Volunteers will visit the laboratory three times and receive either a placebo

or a 150mg dose of DehydraTECH-CBD, three times daily. The results of this study will contribute to the understanding of the effectiveness of patented DehydraTECH-processed CBD as a potential novel anti-hypertensive agent through the course of a full day of monitoring, which is expected to be complementary to the shorter-term monitoring in HYPER-H21-1. Study design for HYPER-H21-2 is complete and university hospital and ethics board approvals are pending, following which the Company will be able to provide additional details on expected timing of commencement of subject recruitment and dosing.

HYPER-H21-3 is also a double-blinded, placebo controlled, randomized human clinical study that has been added to Lexaria's hypertension program to complement the data set the Company intends to build. This study is designed to monitor effectiveness of a 300 mg dose of DehydraTECH-CBD relative to placebo on blood pressure in volunteers under conditions of hypoxic pulmonary vasoconstriction. Data from this study may demonstrate utility of DehydraTECH-CBD for blood pressure reduction in circumstances where pulmonary edema/hypertension results as occurs, for instance, when people travel to high altitude regions of the world. Study design for HYPER-H21-3 is complete and university hospital and ethics board applications are under development and should be submitted shortly. Once approvals are received the Company will be able to provide details on timing of executing this study.

The five studies in Lexaria's 2021 hypertension program are expected to generate data required to further support the validity of using DehydraTECH-processed CBD as a potential hypertension treatment across various applications. Lexaria has received 18 granted patents internationally, including issuances in the European Union and Australia specifically to use DehydraTECH-processed CBD to treat heart disease.

### **DehydraTECH with Antivirals for COVID-19**

As referenced in Lexaria's announcements on December 22, 2020 and February 1, 2021, VIRAL-C21-3 study is designed to evaluate the relative antiviral activity of certain DehydraTECH formulations in an effort to kill the virus in an established cell culture model of SARS-CoV-2 infected cells. This study protocol design is now complete and commencement of the laboratory work is expected in March, as previously announced.

Lexaria relies on applied R&D programs to generate confirmatory results and data evidencing improved drug delivery characteristics that enable pursuit of commercial opportunities and/or corporate relationships. As such, Lexaria considers these applied R&D studies to be a vital early step in establishing commercial relationships with potential industry partners to utilize DehydraTECH within their existing product lines or in the development of new product lines.

Applied R&D studies often also provide test data that support existing patent applications and, at times, produce data that could support additional new patent applications. (Under Lexaria's identification protocols, "A21" designates a 2021 animal study, whereas "H21" designates a 2021 human study and "C21" designates a cell culture study.)

All studies referenced within this press release are fully funded from existing Company resources

### **About Lexaria Bioscience Corp.**

Lexaria Bioscience Corp.'s proprietary drug delivery technology, DehydraTECH™, improves the way active pharmaceutical ingredients (APIs) enter the bloodstream by promoting healthier oral ingestion methods and increasing the effectiveness of fat-soluble active molecules, thereby lowering overall dosing. The Company's technology can be applied to many different ingestible product formats, including foods, beverages, oral suspensions, tablets, and capsules. DehydraTECH has repeatedly demonstrated since 2016 with cannabinoids and nicotine the ability to increase bio-absorption by up to 5-10x, reduce time of onset from 1 - 2 hours to minutes, and mask unwanted tastes; and is planned to be further evaluated for orally administered bioactive molecules, including anti-virals, cannabinoids, vitamins, non-steroidal anti-inflammatory drugs (NSAIDs), and nicotine. Lexaria has licensed DehydraTECH to multiple companies including a world-leading tobacco producer for the development of smokeless, oral-based nicotine products and for use in industries that produce cannabinoid beverages, edibles, and oral products. Lexaria operates a licensed in-house research laboratory and holds a robust intellectual property portfolio with 18 patents granted and approximately 60 patents pending worldwide. For more information, please visit [www.lexariabioscience.com](http://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, 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.

*The CSE has not reviewed and does not accept responsibility for the adequacy or accuracy of this release.*

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