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# Lexaria Files Pre-IND Meeting Request Letter with U.S. FDA

**KELOWNA, BC / ACCESSWIRE / June 6, 2022 /**Lexaria Bioscience Corp. (Nasdaq:LEXX) (Nasdaq:LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms is pleased to announce it has successfully filed a pre-Investigational New Drug ("IND") meeting request letter with the U.S. Food and Drug Administration ("FDA"). The FDA has already responded to and confirmed Lexaria's filing. A target date of July 30, 2022, has been provided to Lexaria, subject to certain conditions being met.

The request for a pre-IND meeting formally initiates communications with the FDA regarding development of Lexaria's DehydraTECH-CBD for the treatment of hypertension. The purpose of the pre-IND meeting will be to confirm the details and acceptability of Lexaria's ongoing IND-enabling development program to be completed thereafter prior to proceeding with its full IND application filing expected in late 2022 / early 2023.

"We are excited to take this important first regulatory step with the FDA for the development of our DehydraTECH-CBD for the treatment of hypertension," said John Docherty, President of Lexaria. "Submission of this request letter initiates formal communication with the FDA regarding our IND clinical trial plans, in order to help define the critical path for clinical development and marketing approval of our potentially very significant new hypertension therapeutic."

In pre-clinical and exploratory clinical studies conducted to-date, Lexaria has repeatedly evidenced efficacy in utilizing DehydraTECH-CBD to reduce blood pressure while avoiding negative serious adverse effects. Efficacy and lack of negative side effects are two major objectives of FDA-registered clinical studies.

Lexaria will update progress on its FDA program for DehydraTECH-CBD when there are material developments.

**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 bio-absorption when administered intraorally and topically.

**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 blood pressure 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 thehighest 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 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 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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