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Lexaria Announces Positive Feedback from Pre-IND Meeting with FDA on DehydraTECH-CBD for Hypertension

- ***Significant Milestone Achieved in Commercial Product Development Program***
- ***Abbreviated 505(b)(2) Strategy Confirmed as an Appropriate NDA Pathway***

KELOWNA, BC / ACCESSWIRE / August 10, 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 received a positive full written response from the Food and Drug Administration ("FDA") from its pre-Investigational New Drug ("Pre-IND") meeting regarding DehydraTECH-CBD for the treatment of hypertension.

The FDA confirmed that it agreed with Lexaria's proposal to pursue a505(b)(2) new drug application ("NDA") regulatory pathway for its program which is advantageous because this abbreviated pathway, as it is often described, typically enables a faster route to commercial approval than the traditional 505(b)(1) NDA pathway.

Lexaria's proposed Phase Ib clinical protocol for DehydraTECH-CBD for treatment of a target of 100 patients with hypertension was received favorably by the FDA, with a view to opening the IND application to allow Lexaria to work towards full registration of DehydraTECH-CBD for treatment of hypertension.

"We are very pleased to have received comments from the FDA toward opening our IND program and we will be executing FDA-confirmed IND-enabling work immediately," said John Docherty, President of Lexaria Bioscience Corp. "We were delighted that our proposals were very well received by the FDA and the feedback received will be very helpful in compiling and filing our IND application as the next major regulatory step we are focused on moving forward."

Additionally, as part of the communication with FDA, it agreed that additional non-clinical studies are not required prior to initiation of the DehydraTECH-CBD IND program, given the compelling data already presented by Lexaria and others regarding the safety and tolerability of CBD. This supports Lexaria's long-held belief that its recent human clinical study program would be supportive of our eventual FDA registration pursuits.

As a result of the favorable FDA response, Lexaria expects to remain on track to file its full IND application with the FDA by late 2022 / early 2023 as previously announced. This is up to 6-9 months sooner than if the FDA had required modifications in Lexaria's current IND-enabling work plan, such as performance of additional non-clinical study work.

DehydraTECH-CBD is protected by multiple patents in the USA and internationally and has received specific patent protection in both the EU and Australia for use in the treatment of heart disease. Lexaria continues to investigate all opportunities within the heart disease sector, including hypertension, arterial stiffness, and more.

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 26 patents granted and roughly 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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