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# Lexaria Bioscience Comments on FDA Statement on Novel Nicotine Replacement Therapies

**KELOWNA, BC / ACCESSWIRE / February 26, 2019 /**Lexaria Bioscience Corp. (OTCQX: LXRP) (CSE: LXX) (the "Company" or "Lexaria"), a drug delivery platform innovator, comments on the February 21, 2019 U.S. Food & Drug Administration ("FDA") statement outlining the development of safe and effective novel nicotine replacement therapies to help smokers quit cigarettes, and the FDA draft guidance issued: "*Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products*".

Lexaria has recently partnered with a world-leading tobacco company that has licensed the Company's DehydraTECH$^{TM}$ technology to develop novel oral nicotine products utilizing Lexaria's technology that could harmonize with the evolving FDA strategy. FDA Commissioner Scott Gottlieb, M.D., issued a statement regarding additional steps by the FDA to support novel nicotine replacement therapies, which contained the following excerpts:

*"More than 54 years after the landmark Surgeon General's report on smoking and health, tobacco use - primarily cigarette smoking - remains the leading cause of preventable disease and death in the U.S., responsible for 480,000 premature deaths each year. Why? Because cigarettes are incredibly addictive.*

*"Most adult smokers want to quit, and nearly half try to do so every year. But nicotine, which a cigarette efficiently delivers through the lungs and to the brain in less than 10 seconds, draws many people back despite their desire to stop.*

*"While nicotine keeps smokers addicted, it's the smoke and the 7,000 chemicals contained in it that causes the disease and death. That's why a key element of our comprehensive plan to significantly reduce tobacco-related disease and death is recognizing that nicotine, while highly addictive, is delivered through products along a continuum of risk with combustible cigarettes at one end, and nicotine replacement therapy (NRT) products at the other. In particular, NRT products, which are designed to safely reduce withdrawal symptoms, including the nicotine craving associated with quitting smoking, are generally considered to double the likelihood of a successful quit attempt. Quitting smoking can lower a person's chances of having lung disease, heart disease or getting certain types of cancer.*

*"Most existing NRTs such as gums, patches and lozenges have been approved for more than 30 years. They have played an important role in providing adults with tools to help quit smoking, in a manner that doesn't require cutting themselves off immediately and entirely*

*from nicotine. Now, we have an opportunity to build on these NRTs, with novel products that may provide an opportunity to save even more lives by empowering adults to safely and effectively quit smoking.*

*"Novel products with different characteristics or routes of nicotine delivery have the potential to offer additional opportunities for health-concerned smokers interested in quitting."*

The entire FDA statement can be found here, or at www.fda.gov.

The FDA has also issued draft guidance for industry "*Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products*" to assist sponsors in the clinical development of nicotine replacement therapy drug products. The guidance reflects the FDA's current recommendations regarding overall development programs to support NRT drug products for smoking cessation and related chronic indications.

As previously announced on January 15, 2019, Lexaria has partnered with the world's most progressive tobacco company that has licensed DehydraTECH and is funding pioneering research and development ("R&D") into novel methods of delivering nicotine without the risks of combustion. Positive results of this R&D program could provide nicotine products that help to meet the goals elucidated within the FDA's statement and guidance, especially relating to oral administration. Lexaria Nicotine LLC will earn royalties on DehydraTECH enabled products sold by its partner tobacco company.

Lexaria has already demonstrated that its patented DehydraTECH technology is effective at delivering nicotine to the bloodstream, in an edible format, in as little as 2 minutes in animal tests reported on August 7, 2018. That same study showed Lexaria's technology delivered 90.2% more nicotine by the 10-minute mark of the study (95% CI; p=0.044) compared to a positive control. Furthermore, nicotine quantities delivered into the brain using its technology ranged from 195%-560% greater than controls with peak concentrations achieved as much as four times faster. Collectively, these results demonstrated the ability of Lexaria's technology to improve nicotine delivery efficiency relative to conventional oral administration. Lexaria is highly confident that DehydraTECH has the potential of meeting FDA goals of reducing the quantity of nicotine in each serving while still satisfying the consumer.

As the FDA has noted within its statement, most smokers fail to quit cigarette smoking despite their desire to do so. Lexaria is of the view that most smokers require an effective alternative nicotine delivery method to empower them to make their best personal choice related to nicotine use. It is widely understood that it is the inhalation of combusted gases and chemicals involved in burning cigarettes that is responsible for most adverse health consequences related to smoking.

Lexaria's technology could offer a method of delivering nicotine that preserves consumer choice, avoids the most serious health consequences of smoking cigarettes, and harmonizes with current FDA policies. As such, Lexaria supports the FDA statement on novel nicotine replacement therapies.

**About Lexaria**

Lexaria Bioscience Corp. has developed and out-licenses its disruptive delivery technology that promotes healthier ingestion methods, lower overall dosing and higher effectiveness of

lipophilic active molecules. Lexaria has multiple patents pending in over 40 countries around the world and has patents granted in the USA and in Australia for utilization of its DehydraTECHTM delivery technology. Lexaria's technology provides increases in intestinal absorption rates; more rapid delivery to the bloodstream; and important taste-masking benefits, for orally administered bioactive molecules including cannabinoids, vitamins, non-steroidal anti-inflammatory drugs (NSAIDs),nicotine and other molecules.

www.lexariabioscience.com

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This release includes forward-looking statements. Statements which are not historical facts are forward-looking statements. The Company makes forward-looking public statements concerning its expected future financial position, results of operations, cash flows, financing plans, business strategy, products and services, competitive positions, growth opportunities, plans and objectives of management for future operations, including statements that include words such as "anticipate," "if," "believe," "plan," "estimate," "expect," "intend," "may," "could," "should," "will," and other similar expressions are forward-looking statements, including but not limited to: that any additional stock warrants or stock options will be exercised. 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 other factors will not affect the accuracy of such 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, managing and maintaining growth, the effect of adverse publicity, litigation, competition, the patent application and approval process and other factors which may be identified from time to time in the Company's public announcements and filings. There is no assurance that existing capital is sufficient for the Company's needs or that it will be able to raise additional capital. There is no assurance that Lexaria will successfully complete any other contemplated or existing technology license agreements; or that results from any studies will be favorable or in any way support future business activities of any kind. Scientific R&D is often unpredictable and unanticipated results could emerge from any study and have a material impact. There is no assurance that any planned corporate activity, scientific study, R&D, business venture, or initiative will be pursued, or if pursued, will be successful. 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). TurboCBD™, DehydraTECH™ technology and ViPova™ products are not intended to diagnose, treat, cure or prevent any disease.

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

**SOURCE:** Lexaria Bioscience Corp.