

Lexaria Summarizes Successful Antiviral Drug Studies and Ongoing Strategy

All objectives evaluating DehydraTECH™ drug delivery platform successfully achieved

KELOWNA, **BC / ACCESSWIRE / July 22**, **2021/** Lexaria Bioscience Corp. (NASDAQ:LEXX)(NASDAQ:LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms is pleased to review its successful 2021 antiviral drug program to date and summarize expected next steps.

Lexaria's objectives in its 2021 antiviral drug examination program thus far have been to determine whether:

- DehydraTECH processing of compounds from leading classes of antiviral drugs for SARS-CoV-2/COVID-19, HIV/AIDS and other infectious diseases could exhibit evidence of superior oral absorption relative to controls,
- DehydraTECH processing of those compounds would preserve expected viral inhibitory performance upon efficacy testing in infected mammalian cells, and
- DehydraTECH does not alter nor degrade the drug molecules chemically as to create new molecular entities that could be challenging to guide through the regulatory approval process.

All three of these objectives have been met.

Lexaria has successfully tested and published summary results on five compounds from three antiviral drug classes, and in each of these drug classes has evidenced significant gains with up to a three-fold increase in oral drug delivery into the bloodstream ("Area Under the Curve" or "AUC") upon animal testing when processed with DehydraTECH:

Drug	Drug Class	AUC DehydraTECH Delivery Improvement (hr·ng/mL)
<u>Efavirenz</u>	RTI	42% (p=0.028)
<u>Darunavir</u>	PI	54% (p=0.036)

Remdesivir	RTI	82% (p=0.12)
(GS-441524)		
Colchicine	ТРМІ	167% (p=0.0028)
<u>Ebastine</u>	PI	204% (p=0.027)

Protease Inhibitors ("PI"): Darunavir and Ebastine (AKA an antihistamine and 3CL or SARS-CoV-2 main protease "MPro" inhibitor)

Reverse Transcriptase Inhibitors ("RTI"): Efavirenz (AKA a non-nucleoside RTI or "NNRTI") and Remdesivir (AKA a nucleotide RTI or "NtRTI"; quantified in its nucleoside analogue metabolite form GS-441524)

Tubulin Polymerization and Microtubule Inhibitor ("TPMI"): Colchicine (AKA an anti-inflammatory)

Lexaria believes that the absorption gains it has demonstrated with the above compounds from their respective antiviral drug classes could have significant commercial potential given the fact that many antiviral drugs exhibit diminished oral bioavailability in their available forms today due to poor intestinal uptake and/or significant liver biotransformation. The DehydraTECH delivery system is designed to overcome this bioavailability issue.

For example, drugs like colchicine in its currently available oral form demonstrate bioavailability of <u>about 45</u>%, and are also known to have a <u>narrow therapeutic index</u>, meaning that the distinction between toxic and non-toxic doses is marginal. There could be significant benefits in allowing its dosing to be reduced while maintaining therapeutic delivery levels. DehydraTECH formulations of antiviral compounds such as colchicine have the potential to lead to significantly improved bioavailability while allowing for lower overall dosing requirements and improved safety and tolerability. The majority of drugs that are currently delivered via injection could also experience lower costs of administration and larger market potential if delivery characteristics were enhanced sufficiently to allow for oral dosing.

The next steps in Lexaria's DehydraTECH antiviral drug testing program are expected to include, but not be limited to, larger *in vivo* efficacy evaluations in animals infected with SARS-CoV-2, HIV or other infectious disease-causing viruses, which Lexaria is planning, subject to further investigation to select lead compounds based on our work to-date for this effort. The Company will release further plans and results related to these upcoming studies as they become available.

Lexaria is working diligently on a comprehensive, multi-pronged program that is intended to demonstrate pivotal proof-of-concept safety, efficacy and formulation/scalability feasibility data to prospective pharmaceutical industry partners with a view to creating opportunities for expanded, collaborative product development. The Company is interested in pursuing strategic collaboration opportunities with established pharmaceutical industry partners who

may be interested in incorporating DehydraTECH technology with antiviral drugs including and/or similar to those that are currently being investigated. Lexaria would like to evidence that DehydraTECH works to enhance the oral delivery characteristics of the drugs mentioned above and potentially others which are used to fight many virus triggered diseases, including but not limited to shingles, influenza and viral forms of gastroenteritis, hepatitis, meningitis, and pneumonia.

Antiviral Drug Background and DehydraTECH Formulation Strategy

The first antiviral drug was approved for use in the USA in 1963, and over 90 additional antiviral drugs have been approved since, with thousands of other antiviral inhibitors having been proposed. Eleven of the approved drugs are used to treat more than one infectious disease, illustrating that some of these drugs are effectively used for multiple applications.

Antiviral drugs treat those who have been infected and try to preserve life; whereas antiviral vaccines are administered to those who are not infected in an effort to prevent or lessen the severity of subsequent infection.

Of note, "antiviral drugs from the same drug group share similar mechanisms of drug action to inhibit viral reproduction <u>during the viral life cycle</u>" This phenomenon is a crucial component to Lexaria's strategy of evidencing that DehydraTECH improves the delivery characteristics of many drugs from the classes Lexaria has investigated, potentially assisting in their efficacy for both their original approved use, as well as for use treating additional health indications if/when that delivery performance has been enhanced.

For example, there are <u>six main classes</u> of antiviral drugs used to treat HIV, including drugs from the PI and RTI classes, above. There are 37.7 million people currently known to be infected with HIV and 36.3 million <u>people have died</u> from HIV/AIDS since the beginning of the epidemic, roughly equal to the entire population of Canada. There are over <u>200 drugs approved by the FDA</u> to treat HIV/AIDS. Because of the massive regulatory and scientific response to the onset of HIV, this disease is thankfully killing fewer people now than in the past, although significant demand remains for safe and effective HIV/AIDS therapies that can be used on a chronic treatment basis to preserve life.

Influenza is caused by viruses even though vaccines have been widely available for years and remain the #1 recommended method to prevent infection. Despite that, between 290,000 and 650,000 people die every year from seasonal influenza. The 1918-19 influenza epidemic is thought to have killed up to 50 million people, and the 1958 and 1968 influenza epidemics are thought to have killed between 1 and 4 million people each. There are only 4 drugs approved by the FDA to treat influenza; three of them belong to the Neuraminidase Inhibitors class and must be administered by injection, and one belongs to the PA endonucleases inhibitor class and is taken as an oral tablet.

Over 189 million people have been infected by SARS-CoV-2 in the current global epidemic, and over 4 million <u>have died to date</u>. It is not known today if or when infections and deaths will stop. Many drugs are being investigated for use in treatment of SARS-CoV-2, including but not limited to compounds from each of the PI, RTI, and TPMI drug classes. Only remdesivir has received emergency use authorization from the FDA for treatment of SARS-CoV-2.

Regardless of the efficacy and availability of vaccines to prevent many viral infections

including influenza vaccines that have been widely <u>available since 1945</u>, thousands of people die every year because they are infected with viruses while unvaccinated, or live in large areas of the world where vaccines are not available. It is currently estimated that <u>over 99%</u> of the over <u>200,000 deaths</u> in the US since January 1, 2021 from SARS-CoV-2 have occurred in unvaccinated victims, demonstrating the vital current need for successful treatment options for those who are unvaccinated.

Based on all these facts, the need and demand for effective antiviral drugs via oral delivery that are available to all, has never been more profound than today. Lexaria has progressed significantly in evidencing that its DehydraTECH delivery technology can sufficiently enhance the usable fraction of known antiviral drugs that reach the bloodstream so that they can safely and more effectively do what they are designed to accomplish. Lexaria continues to evaluate the data generated from its 2021 antiviral drug program and will make an announcement regarding next steps as soon as possible.

The Company is not making any express or implied claims that its products have the ability to eliminate, cure or contain the COVID-19 pandemic (or SARS-CoV-2 or novel Coronavirus) or any other virally induced diseases at this time.

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 inhouse research laboratory and holds a robust intellectual property portfolio with 20 patents granted and approximately 60 patents pending worldwide. For more information, please visit www.lexariabioscience.com.

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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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