



Revive Therapeutics Provides Update From FDA Meeting for Long COVID Diagnostic Product

TORONTO, June 10, 2024 -- Revive Therapeutics Ltd. (“Revive” or the “Company”) (OTCQB: RVVTF) (CSE: RVV) (FRANKFURT:31R), a specialty life sciences company focused on the research and development of therapeutics and diagnostics for infectious diseases, medical countermeasures, and rare disorders, announced today an update on the meeting written responses received by the Company from the U.S. Food & Drug Administration (“FDA”) of the Revive LC POC Lateral Flow Test Kit (the “Product”) for feedback on the classification, development and regulatory submission strategy for a point-of-care in vitro diagnostic device that aids in the detection of post COVID-19 conditions. The FDA has determined that the Product should follow the De Novo regulatory pathway, and the Company would be required to conduct a clinical study for the De Novo submission for possible approval.

“We agree with the FDA feedback and with their recommendations that provides a pathway for the development of the Revive LC POC Lateral Flow Test Kit in the detection of long COVID,” said Michael Frank, CEO of Revive. “We will now discuss the proposed development plan and timelines with potential contract manufacturers.”

The Company, under its wholly-owned subsidiary Revive Diagnostics Inc., is advancing the Product as a potential blood biomarker diagnostic that characterizes long COVID. The discovery of the biomarkers identified by a research team at Lawson, led by Dr. Douglas Fraser, was recently published in the journal, *Molecular Medicine*¹.

Currently, there is no FDA-approved clinical diagnosis of long COVID and it is estimated to occur in at least 10% of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. More than 200 symptoms have been identified with impacts on multiple organ systems² — including fatigue, brain fog, difficulty breathing, and cardiovascular symptoms ranging from chest pain and arrhythmias to sudden cardiac death—but it remains a diagnosis of exclusion with an unknown biological basis³.

The Company entered into a license agreement with Lawson Health Research Institute for the worldwide exclusive rights to the intellectual property of novel blood biomarkers that characterize long COVID. The intellectual property includes PCT/CA2023/050145 entitled “Blood Biomarkers in Long-COVID19”; PCT/CA2023/051292 entitled “Biomarkers in Long-COVID19”; and US Provisional Patent Application No. 63/433,425 entitled “Diagnosis and Treatment of Long-COVID”.

About Revive Therapeutics Ltd.

Revive Therapeutics is a life sciences company focused on the research and development of therapeutics and diagnostics for infectious diseases, medical countermeasures, and rare disorders. Revive prioritizes its drug development efforts to take advantage of several regulatory incentives awarded by the FDA, such as Emergency Use Authorization, Orphan Drug, Fast Track, and Breakthrough Therapy designations. Currently, the Company is exploring the use of Bucillamine for the potential treatment of nerve agent exposure and long COVID. Revive is also advancing the development of Psilocybin-based therapeutics through various programs. For more information, visit www.ReviveThera.com.

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This press release contains ‘forward-looking information’ within the meaning of applicable Canadian securities legislation. These statements relate to future events or future performance. The use of any of the words “may”, “could”, “intend”, “expect”, “believe”, “will”, “projected”, “estimated” and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on Revive’s current belief or assumptions as to the outcome and timing of such future events. Forward looking information in this press release includes information with respect to the Company’s cannabinoids, psychedelics and infectious diseases programs. Forward-looking information is based on reasonable assumptions that have been made by Revive at the date of the information and is subject to known and unknown risks, uncertainties, and other factors that may cause actual results or events to differ materially from those anticipated in the forward-looking information. Given these risks, uncertainties and assumptions, you should not unduly rely on these forward-looking statements. The forward-looking information contained in this press release is made as of the date hereof, and Revive is not obligated to update or revise any forward-looking information, whether as a result of new information, future events or

otherwise, except as required by applicable securities laws. The foregoing statements expressly qualify any forward-looking information contained herein. Reference is made to the risk factors disclosed under the heading "Risk Factors" in the Company's management's discussion and analysis for the three and nine months ended March 31, 2024 ("MD&A"), dated May 28, 2024, which is available on the Company's profile at www.sedarplus.ca.

Source:

1. "Elevated vascular transformation blood biomarkers in Long-COVID indicate angiogenesis as a key pathophysiological mechanism." *Molecular Medicine* 28, 122 (2022). [London researchers discover novel method to diagnose long COVID | Lawson Health Research Institute \(lawsonresearch.ca\)](https://doi.org/10.1038/s41579-022-00846-2)
2. Davis, H.E., McCorkell, L., Vogel, J.M. et al. Long COVID: major findings, mechanisms and recommendations. *Nat Rev Microbiol* 21, 133–146 (2023). <https://doi.org/10.1038/s41579-022-00846-2>; access <https://www.nature.com/articles/s41579-022-00846-2>
3. "Proteins In The Blood Hint At Biological Basis Of Long COVID", *Clinical Research News*, August 11, 2023, <https://www.clinicalresearchnewsonline.com/news/2023/08/11/proteins-in-the-blood-hint-at-biological-basis-of-long-covid>