Revive Therapeutics Provides Update of Phase 3 Clinical Study for Bucillamine in the Treatment of COVID-19

TORONTO, March 20, 2023 -- 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 for medical needs and rare disorders, announced today an update on the Company's U.S. Food & Drug Administration ("FDA") Phase 3 clinical trial (the "Study") (NCT04504734) to evaluate the safety and efficacy of Bucillamine, an oral drug with anti-inflammatory and antiviral properties in patients with mild to moderate COVID-19.

On March 8th, 2023, the Company announced that it had received the Type C meeting written responses from the FDA to obtain agreement on the proposed protocol endpoints for the Company's Study. The FDA recommended that the Company's proposed primary symptom-based endpoint should cover the evaluation of time to sustained recovery assessed over an appropriate duration, evidence of subjects experiencing resolution of COVID-19 related symptoms and the element of sustained symptom resolution.

After a further in-depth review and analysis of the FDA recommendations with members of the Company's clinical trial team, including its statistician, regulatory affairs, medical affairs, and clinical research advisors, the Company has decided that in the best interest of the Study to preserve and not compromise the integrity of the Study and keep the blinded data intact to support a potential FDA approval in the future. As such, the Company will remain with the current Study protocol's primary endpoint of *proportion of patients meeting a composite endpoint of hospitalization or death from time of first dose through Day 28 following randomization*. Although the Study was originally designed for a '*hospitalization or death'* primary endpoint, and it completed enrollment of almost three-quarters of the Study's recruitment goal and recorded specific clinical symptoms (i.e. cough, fever, heart rate, and oxygen saturation), the Study was not designed to take into account all of the symptom assessments and supporting data outlined in the FDA guidelines to warrant a primary symptom-based endpoint for COVID-19 studies.

With the shift in COVID-19 clinical outcomes observed over the course of the pandemic, many patients with COVID-19 were either asymptomatic or experienced mild to moderate illness and could be managed in the outpatient setting. The Company made efforts with the FDA to allow for specific primary symptom-based endpoints, which were aligned with the Study's available Pre-Dose selection data, such as *time to resolution from COVID-19 via the polymerase chain reaction test* and *proportion of participants with improvement in at least two COVID-19 related clinical symptoms on or before Day 14*. As such, it was now determined by the Company's advisors and clinical team that any deviation from the Study's original primary endpoint ('*hospitalization or death'*) and any unblinding of the Post-Dose selection data of approximately 500 subjects that were randomized in the current Study would jeopardize any chance of potential future regulatory approval. As previously announced, the Data Safety Monitoring Board ("DSMB") reviewed the Study's Post-Dose selection data and supported the continuation of the Study in its last meeting as there were no serious adverse events or safety concerns reported.

As a result, the Company is committed to advancing the clinical and commercial development of Bucillamine and plans to pursue the following activities:

1. Continue discussions with the FDA on a pathway for future potential regulatory approval under the current Study's objectives, which the FDA and DSMB continue to support;
2. Work with the Study's current participating clinical sites and potential new clinical sites to develop a defined recruitment plan that prioritizes subjects recognized to be at higher risk for developing severe COVID-19 to achieve the Study's objectives;
3. Determine potential opportunities of unblinding additional data related to the Study for evaluation to support future discussions with the FDA, and further studies for Long COVID or COVID symptom-related conditions, which the FDA provided advice to pursue, and various infectious and respiratory disorders;
4. Develop reformulation strategies of Bucillamine to expand on its potential therapeutic utility targeting rare disorders that may come with regulatory incentives awarded by the FDA, such as orphan drug (i.e. ischemia-reperfusion injury, cystinuria), fast track, and breakthrough therapy designations; and
5. Secure alliances with strategic partners, including pharmaceutical companies, to achieve Bucillamine's full commercial potential.

The Company is not making any express or implied claims that its product has the ability to eliminate or cure COVID-19 (SARS-2 Coronavirus) at this time.

About Revive Therapeutics Ltd.

Revive is a life sciences company focused on the research and development of therapeutics for infectious diseases and rare disorders, and it is prioritizing drug development efforts to take advantage of several regulatory incentives awarded by the FDA such as Orphan Drug, Fast Track, Breakthrough Therapy and Rare Pediatric Disease designations. Currently, the Company is exploring the use of Bucillamine for the potential treatment of infectious diseases, with an initial focus on severe influenza and COVID-19. With its acquisition of Psilocin Pharma Corp., Revive is advancing the development of Psilocybin-based therapeutics in various diseases and disorders. Revive's cannabinoid pharmaceutical portfolio focuses on rare inflammatory

diseases and the company was granted FDA orphan drug status designation for the use of Cannabidiol (CBD) to treat autoimmune hepatitis (liver disease) and to treat ischemia and reperfusion injury from organ transplantation. For more information, visit www.ReviveThera.com.

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