Revive Therapeutics Provides Update on Phase 3 Clinical Trial for Bucillamine in COVID-19

- *Screened approximately 700 subjects and expanding to Eastern Europe, including Turkey, as part of its clinical diversification plans to support global regulatory approvals*
- *No serious adverse events and safety concerns reported to date in the Phase 3 clinical trial*
- *Expected to complete enrollment in Q1-2022*

TORONTO, Dec. 29, 2021 (GLOBE NEWSWIRE) -- 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, is pleased to provide 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.

To date, the Study has screened approximately 700 subjects. The Independent Data and Safety Monitoring Board supported the continuation of the Study in its last meeting as there were no serious adverse events or safety concerns.

In light of Phase 3 clinical studies and FDA approvals of oral antiviral treatments by Pfizer and Merck, it was evident that to ensure a diversified patient population to support future global regulatory submissions for Bucillamine, including the FDA, the Company has decided to fill a part of its patient enrollment quota outside of the U.S. and target Eastern Europe, such as in Turkey, where the reported cases of COVID-19 are high with 32,176 new COVID-19 infections reported on December 28, 2021 (https://covid19.saglik.gov.tr/TR-66935/genel-koronavirus-tablosu.html). In addition, the Company in collaboration with Delta Health will add research sites from the largest hospital group in Turkey, MLP Care and Istinye University, which has 30 directly owned hospitals in 15 cities and its affiliated university medical centers (including state-of-the-art certified laboratories) for a combined capacity of over 6000 in-patient hospital beds across Turkey.

As a result of the Company’s plans to diversify its patient population globally, incorporate viral load and anti-inflammatory markers, and its ongoing discussions with international pharmaceutical companies seeking to obtain commercial rights to Bucillamine as a treatment for COVID-19 in various countries in Europe, India and Asia, the Phase 3 clinical study enrollment completion period is expected in Q1-2022. The Company still expects to file an Emergency Use Authorization (“EUA”) with the FDA if the blinded results provide evidence to the DSMB’s final review to recommend to pursue EUA for Bucillamine to treat mild to moderate COVID-19.

Michael Frank, CEO of the Company commented, "We are now focused on completing the Phase 3 study in a manner which will provide practical antiviral, anti-inflammatory and a diversified patient population. With the recent onset of the Omicron variant we have made some of the above adjustments to the trial.”

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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