Resverlogix Receives Ethics Approval for Canadian Sites in Apabetalone COVID-19 Clinical Trial

Study Approval Paves the Way for Trial Participants to Begin Taking Apabetalone

CALGARY, Alberta, Oct. 12, 2021 (GLOBE NEWSWIRE) -- Resverlogix Corp. ("Resverlogix" or the "Company") (TSX:RVX), today announces the approval of its COVID-19 clinical trial of apabetalone by the Health Research Ethics Board (HREB) – Biomedical Panel at the University of Alberta. This approval allows for recruitment in the trial to commence.

“The ethics board approval is an important step towards bringing apabetalone to market to help fight the ongoing COVID-19 pandemic,” said Donald McCaffrey, Resverlogix’s President & CEO. “The approved trial design closely follows the World Health Organization’s blueprint for best practices in COVID-19 clinical trials, and meets all requirements to safely and ethically evaluate apabetalone as a potential new therapy.”

The Health Research Ethics Board assesses all matters required by section 50(1)(a) of the Health Information Act. Subject consent for access to identifiable health information is required for the research described in the ethics application, and appropriate procedures for such consent have been approved by the HREB - Biomedical Panel.The final authorization from the HREB – Biomedical Panel consisted of the evaluation of 12 complex required documents, including: approved protocol, patient consent forms, investigator brochures/product monographs, and the Health Canada no objection letter, to name a few.

Trial Overview

Study participants will be made up of patients hospitalized with confirmed COVID-19 cases. Participants will either receive twice daily doses of apabetalone for up to 4 weeks alongside standard of care, compared to standard of care alone. The primary outcome measure of the study will be change in the World Health Organization (WHO) Ordinal Scale for Clinical Improvement. A total of 100 patients are expected to be enrolled at multiple sites in Canada and Brazil. The full study protocol can be found on clinicaltrials.gov.

About Apabetalone

Apabetalone (RVX-208), is a first-in-class, epigenetic small molecule, or gene regulating, therapeutic candidate. It is a selective BET (**b**romodomain and **e**xtra-**t**erminal) inhibitor, which works in preventing disease by turning genes on and/or off through regulation of gene expression. The prevalence of BET proteins in the human body allows apabetalone, through its unique mechanism of action, to simultaneously target multiple disease-causing biological processes while maintaining a well described safety profile – leading to a new way to treat chronic disease.

Cardiology:

In February 2020, apabetalone became the first therapy of its kind to receive Breakthrough Therapy Designation by the US Food and Drug Administration (FDA) – for a major cardiovascular indication – following the groundbreaking findings from the BETonMACE Phase Three study. Data from BETonMACE showed apabetalone can potentially prevent major adverse cardiac events among high-risk cardiovascular disease patients who also have type 2 diabetes mellitus.

Covid-19:

On March 23, 2020, Resverlogix launched its COVID-19 program, enlisting world-renowned collaborators. Studies demonstrate that apabetalone has the potential to act against COVID-19 with a unique dual-mechanism: the first pillar of apabetalone’s dual -mechanism is preventing viruses from entering the cells and replicating; the second pillar is averting runaway inflammatory reactions that can cause severe and lasting organ damage. A Phase Two clinical trial is evaluating apabetalone in combination with standard of care for patients hospitalized with COVID-19. Apabetalone treatment could potentially reduce the severity and duration of COVID-19. Apabetalone’s unique dual-mechanism also means that it is likely to show efficacy against COVID-19 variants and may even help fight other related viruses.

Apabetalone is the only drug of its class with a well-established safety record in human clinical trials, with well over 4200 patient-years on drug across 10 clinical trials.

About Resverlogix

Founded in 2001, Resverlogix is a Calgary based late-stage biotechnology company and the world leader in epigenetics, or gene regulation, with the goal of developing first-in-class therapies for the benefit of patients with chronic disease.

Resverlogix is commercializing a new class of epigenetic therapies designed to regulate gene expression, turning disease-associated genes “on” or “off”. We aim to improve patients’ lives by restoring biological functions – altered by serious illnesses such as cardiovascular disease – back to a healthier state.

The Company's clinical program is focused on evaluating the lead epigenetic candidate apabetalone for the treatment of cardiovascular disease and associated comorbidities, and COVID-19.

Resverlogix common shares trade on the Toronto Stock Exchange (TSX:RVX).

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Forward Looking Statements:

This news release may contain certain forward-looking information as defined under applicable Canadian securities legislation, that are not based on historical fact, including without limitation statements containing the words "believes", "anticipates", "plans", "intends", "will", "should", "expects", "continue", "estimate", "forecasts" and other similar expressions. In particular, this news release includes forward looking information related to the potential role of Apabetalone in the treatment of patients with COVID-19 (and potentially other viruses), cardiovascular disease and associated comorbidities and other chronic diseases. Our actual results, events or developments could be materially different from those expressed or implied by these forward-looking statements. We can give no assurance that any of the events or expectations will occur or be realized. By their nature, forward-looking statements are subject to numerous assumptions and risk factors including those discussed in our Annual Information Form and most recent MD&A which are incorporated herein by reference and are available through SEDAR at www.sedar.com. The forward-looking statements contained in this news release are expressly qualified by this cautionary statement and are made as of the date hereof. The Company disclaims any intention and has no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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