Resverlogix Reaches Agreement With FDA for Key Aspects of Apabetalone Registration Enabling Study

CALGARY, Alberta, June 22, 2020 -- Resverlogix Corp. ("Resverlogix") (TSX:RVX) is pleased to announce that the U.S. Food & Drug Administration (FDA) has accepted its BETonMACE2 clinical plan as a registration enabling study with positive implications for Resverlogix and its ongoing partnership discussions. Key written development points from a recent meeting with the FDA include the following:

- Filing of a New Drug Application (NDA) with the FDA is possible following unequivocal efficacy at an interim analysis of BETonMACE2
- All or most BETonMACE2 patients to receive top standard of care, including maximized use of SGLT2 inhibitors (SGLT2i)
- BETonMACE2 to increase enrichment of chronic kidney disease (CKD) patients, potentially including those with lower baseline renal function
- Based on BETonMACE results, the FDA encouraged the evaluation of a non-alcoholic fatty liver disease (NAFLD) subgroup as well as related exploratory endpoints

The purpose of the Comprehensive Multidisciplinary Initial Breakthrough Therapy Designation (BTD) meeting held between the FDA and Resverlogix on June 2, 2020 was to discuss the ongoing development program for apabetalone following receipt of the company's Breakthrough Therapy Designation announced on February 3, 2020.

"I am extremely pleased with the very constructive BTD discussions with the FDA to-date and look forward to our ongoing work and future progress," stated Donald McCaffrey, President & CEO of Resverlogix. "Several customary topics were discussed during our recent meeting with regards to the ongoing development requirements for apabetalone and the eventual filing of a NDA. Significantly, the Company's overall study design for BETonMACE2 – the planned clinical study subsequent to BETonMACE – was accepted by the FDA and we expect this will greatly enhance our current and ongoing partnership discussions."

The FDA recommended that all or most BETonMACE2 participants be on a background of top standard of care, including SGLT2i, as clinically indicated. BETonMACE revealed significant, potential synergy with apabetalone and new diabetes drugs including SGLT2i. Among those receiving SGLT2i, a hazard reduction of 60% in the primary endpoint was seen in patients receiving apabetalone and top standard of care, compared to placebo and top standard of care alone.

In addition, the Company will explore and consider additional criteria for future FDA discussion including lower degrees of renal function than that of BETonMACE participants. BETonMACE patients on apabetalone with an estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73m^2 at baseline saw a 50% hazard reduction in the primary endpoint for this chronic kidney disease subgroup. This was compared to patients receiving placebo and top standard of care alone.

Lastly, additional data analysis from BETonMACE suggests that patients with NAFLD may experience a reduction in major adverse cardiac events and hospitalization for heart failure (MACE+HHF) when on apabetalone and top standard of care. The FDA has encouraged the Company to explore subgroups in BETonMACE2 that could differentially derive benefit from MACE+HHF reduction.

Breakthrough Therapy Designation

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of new drugs to address unmet medical need in the treatment of serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

Expedited programs, including Breakthrough Therapy Designation, help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies' benefits justify their risks, taking into account the seriousness of the condition and the availability of alternative treatment.

About BETonMACE

In the fall of 2019, Resverlogix reported results from its Phase 3 trial BETonMACE. BETonMACE was a clinical trial that tested apabetalone treatment to impact primary MACE on 2,425 CVD patients with diabetes and a recent acute coronary syndrome event. The trial in its primary endpoint of primary MACE in the entire population had a hazard reduction of 18% versus placebo. In the pre-specified CKD sub population, apabetalone significantly reduced both primary MACE and hospitalizations due to congestive heart failure in comparison to placebo with top standard of care. Apabetalone's consistent safety profile was further validated by an analysis of adverse events in BETonMACE, and nine positive reports by the trial's independent Data and Safety Monitoring Board.

About Resverlogix

Resverlogix is developing apabetalone (RVX-208), a first-in-class, small molecule that is a selective BET (bromodomain and extra-terminal) inhibitor. Apabetalone is the first therapy of its kind to have been granted US FDA Breakthrough Therapy Designation – for a major cardiovascular indication – to help facilitate a time-efficient drug development program including planned clinical trials and plans for expediting the manufacturing development strategy.

BET inhibition is an epigenetic mechanism that can regulate disease-causing genes. Apabetalone is a BET inhibitor selective for the second bromodomain (BD2) within the BET proteins. This selective inhibition of apabetalone on BD2 produces a specific set of biological effects with potentially important benefits for patients with high-risk cardiovascular disease, diabetes mellitus, chronic kidney disease, end-stage renal disease treated with hemodialysis, neurodegenerative disease, Fabry disease, peripheral artery disease and other orphan diseases, while maintaining a well described safety profile.

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

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