Resverlogix Receives US FDA Breakthrough Therapy Designation for Apabetalone

CALGARY, Alberta, Feb. 03, 2020 -- Resverlogix Corp. (“Resverlogix” or the "Company") (TSX: RVX) is pleased to announce the U.S. Food & Drug Administration (“FDA”) has granted Breakthrough Therapy Designation for apabetalone in combination with top standard of care, including high-intensity statins, for the secondary prevention of major adverse cardiac events in patients with type 2 diabetes mellitus and recent acute coronary syndrome.

"This extremely exciting development significantly supports our commercialization plans for apabetalone,” said Donald McCaffrey, President and CEO. “The FDA recognizes that apabetalone, in combination with top standard of care therapies, is a novel way to address a major unmet need. This important designation – the first for a major cardiovascular indication – entails working closely with the FDA to facilitate a time-efficient drug development program including planned clinical trials and plans for expediting the manufacturing development strategy for apabetalone. We look forward to working with the FDA on next steps and updating our stakeholders on future material developments.”

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.

BETonMACE

In the fall of 2019, Resverlogix reported results from the groundbreaking Phase 3 trial BETonMACE. Apabetalone treatment significantly reduced hospitalizations due to congestive heart failure in comparison to placebo with top standard of care, as well as improving cardiovascular outcomes in two pre-specified subpopulations including those with chronic kidney disease. Significant improvements in cognition, as measured by Montreal Cognitive Assessment (MoCA) and relative to placebo with top standard of care, were also observed in cardiovascular disease patients with moderate to severe cognitive decline. 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. 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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cognitive disorders, high-risk cardiovascular disease, diabetes mellitus, chronic kidney disease, end-stage renal disease treated with hemodialysis, Fabry disease, peripheral artery disease and other orphan 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.