Resverlogix Provides Update on BETonMACE Phase 3 Trial

Top-line results projected to be available on or about September 30, 2019

Number of MACE increases from 250 to greater than 275

CALGARY, Alberta, Sept. 16, 2019 -- Resverlogix Corp. (“Resverlogix” or the "Company") (TSX:RVX) announced today that, following the completion of final patient safety visits (as reported by the Company on July 8, 2019), the resolution of all outstanding queries is expected within a matter of days, leading to database lock. Following database lock, BETonMACE top-line data is expected to be announced on or about September 30, 2019.

Furthermore, it is projected that the number of narrowly-defined Major Adverse Cardiovascular Events (“MACE”) – defined as a single composite endpoint of cardiovascular death or non-fatal myocardial infarction or stroke – to be used in the primary data analysis, is now estimated to be greater than 275 – compared to the initial calculation of 250 events in the trial’s protocol. In addition, median time on treatment will be approximately 27 months compared to the protocol’s 18-month assumption.

The higher number of MACE increases the powering of BETonMACE (from the original 80% to approximately 85%), improving the likelihood of detecting a significant reduction of the trial’s primary endpoint using the original assumptions of a 0.7 Hazard Ratio with a p-value of <0.05. For clarification, the primary analysis as defined in the statistical analysis plan communicated with the Food and Drug Administration (FDA) will remain a time-to-event analysis.

In addition, we expect that BETonMACE’s full outcomes, pre-specified endpoint data, safety results and clinical implications will be reported and published through major conferences and publications in late-2019 and afterward beginning with the American Heart Association (AHA) meeting in November 2019 in Philadelphia, followed by the Clinical trial on Alzheimer’s Disease (CtAD) meeting in December 2019 in San Diego. Data will also be disseminated at leading nephrology meetings. Further details regarding the Company’s presentation of BETonMACE data at these meetings will be communicated once confirmed.

Loan Extension

The Company also announces that it has entered into an amending agreement with Third Eye Capital (acting as agent for a syndicate of lenders) to extend the maturity date of the Company’s senior secured term loan (the “Loan”) from September 16, 2019 to September 27, 2019. In connection with the amendment, Resverlogix paid an amendment fee of US$50,000. Of the original US$30 million Loan, the remaining principal balance is approximately US$11.5 million. The Company intends to repay the Loan on or before maturity.

BETonMACE

On April 18, 2019, BETonMACE successfully reached 250 projected MACE events, strictly defined as cardiovascular death, non-fatal myocardial infarction and stroke. Final follow-up patient safety visits were reported by the Company on July 8, 2019, marking another important step towards trial completion. Successful data from this trial would enable Resverlogix to proceed towards the regulatory approval and commercialization of its lead drug, apabetalone – a leader in a new class of drugs outside of oncology designed to regulate disease-associated proteins.

Dosing with apabetalone commenced in November 2015 and the trial exceeded full enrollment – with a total of 2,425 study participants – in March 2018. BETonMACE has been reviewed nine times by the trial’s independent Data and Safety Monitoring Board, with no safety issues identified, and has been recommended to continue without any study modifications. The primary endpoint of the BETonMACE trial is designed to show a relative risk reduction of narrowly defined MACE for patients who remain on a high-dose statin therapy and top standard of care. Despite maximized use, current statin therapies manage only about 30% of cardiovascular disease related events leaving a significant market opportunity for apabetalone to address unmet medical need.

The BETonMACE trial is addressing three initial indications – acute coronary syndrome, vascular cognitive dementia and chronic kidney disease – with an addressable market of over 12 million patients in the top 8 markets.

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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