



News Release

Pivotal Therapeutics Inc. Releases Positive Results from Open Label Study of VASCAZEN™

FOR IMMEDIATE RELEASE

September 27, 2011

Woodbridge, Ontario, Canada, September 27, 2011 - Pivotal Therapeutics Inc. (CNSX:PVO) a specialty pharmaceutical company with a focus on the treatment of cardiovascular disease, announced the release of positive results from its open label study of VASCAZEN™ by Dr. George Jackowski, Chairman and Chief Scientific Officer at the *Rodman & Renshaw Annual Global Investment Conference* on September 13th in New York City.

The primary objective of the study was to assess the efficacy and safety of VASCAZEN™, measuring participants' Omega-3 blood levels at two-week intervals. The final results of the study indicate that four capsules per day of VASCAZEN™, providing 3.0g per day of Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA), resulted in a rapid improvement in study participants' Omega-3 blood levels. In addition to the positive results regarding VASCAZEN's™ efficacy, it was also shown to be safe and well tolerated.

"The study found over 84% of participants demonstrated moderate to severe deficiencies in Omega-3 fatty acids, as measured using our Omega-Score™ companion diagnostic test. These results are consistent with published data and literature," says Dr. Jackowski "The rapid increase in study participants' Omega-3 levels following the use of VASCAZEN™ supports Pivotal's further clinical evaluation of our lead product."

Dr. Jackowski also highlighted published study results in the current literature regarding Omega-3 deficiencies and the therapeutic benefits of essential fatty acids in the treatment of cardiovascular disease patients, including the *New England Journal of Medicine*.*

The study, conducted by Pivotal, offered results from the baseline Omega-Score™ assessment in 143 participants: 106 male and 37 female. Findings revealed that over 84% of study participants' baseline Omega-3 levels scored in the "moderate" to "very high risk" range with an average score of 3.4% (very high risk) with similar trends in both the male and female populations.

Findings showed significant and rapid improvement in participants' Omega-Score™ after two weeks with the baseline average of 3.4% (very high risk) increasing to 5.7% (moderate risk). Within four weeks, Omega-3 blood levels increased to an average of 7.9% (low risk) with these levels maintained for the remainder of the study.

"With the presentation of these findings we are confident moving forward with our REVEAL Trial and anticipate its results," comments Rachelle MacSweeney, President of Pivotal Therapeutics.

The REVEAL trial is a 200-patient, randomized, placebo-controlled, double-blind parallel study of Omega-3-deficient cardiovascular patients with elevated triglycerides. The study will assess the effectiveness of Pivotal's lead product VASCAZEN™ by elevating EPA and DHA Omega-3 fatty acids.

** Blood Levels of Long-Chain n-3 Fatty Acids and the Risk of Sudden Death, N Engl J Med, Vol. 346, No. 15 - April 11, 2002*

About Pivotal Therapeutics Inc.

With offices in Toronto, Canada and Boca Raton, Florida, Pivotal Therapeutics is a publicly traded (CNSX: PVO) specialty pharmaceutical company with a focus on the treatment of cardiovascular disease. Pivotal Therapeutics' lead product VASCAZEN™ is a prescription medical food formulated to meet the dietary Omega-3 deficient needs of patients with cardiovascular disease through elevating Eicosapentaenoic (EPA) and Docosahexaenoic (DHA) to levels associated with reduced risk of cardiovascular complications.



VASCAZEN™ is a >90% pure, proprietary EPA:DHA fatty acid formulation, protected by a series of both issued and pending US and foreign patents and commercialized by prescription only. This unique formulation will provide the cornerstone upon which a family of cutting edge combination products, with efficacy across a broad spectrum of cardiac care, will be commercialized.

Disclosure Notice

The information contained in this document is as of September 27, 2011. This press release contains forward-looking statements. Such forward-looking statements are subject to a number of risks, assumptions and uncertainties that could cause Pivotal's actual results to differ materially from those projected in such forward-looking statements. These statements can be identified by the use of words such as "will", "anticipate", "estimate", "expect", "project", "forecast", "intend", "plan", "believe", "project", "potential", and similar expressions with any discussion of future operating or financial performance or events. In particular, factors that could cause actual results to differ materially from those in forward looking statements include the following: Pivotal's inability to obtain additional financing on acceptable terms; growth in costs and expenses; inability to compete with others who provide comparable products; risk that the Company's products will not gain widespread market acceptance; risks relating to the Company's ability to maintain its CSNX listing. Forward-looking statements speak only as of the date made and are not guarantees of future performance. The Company undertakes no obligation to publicly update or revise any forward-looking statements, contained in this document as a result of new information or future events or developments.

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