

News Release

**PIVOTAL THERAPEUTICS VASCAZEN®-REVEAL TRIAL MEETS PRIMARY
AND SECONDARY ENDPOINTS –
VASCAZEN® SHOWS 121% CORRECTION OF AN OMEGA-3 DEFICIENCY ($p < 0.0001$)
WITH A CONCOMITANT 48% REDUCTION IN TRIGLYCERIDES ($p < 0.0005$)**

FOR IMMEDIATE RELEASE

MAY 7, 2013

Woodbridge, Ontario, MAY 7, 2013 - Pivotal Therapeutics Inc. (OTCQX: PVTTF) (CNSX: PVO), a specialty pharmaceutical company with a focus on Omega-3 therapies for cardiovascular disease (CVD) and overall health, presented positive, statistically significant, top-line results from its **VASCAZEN®-REVEAL** trial for the Company's lead product **VASCAZEN®**, a unique >90% pure Omega-3 prescription medical food with a proprietary 6:1 EPA:DHA fatty acid formulation. The results were presented on May 3, 2013 at the American Heart Association's Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) 2013 Scientific Sessions.

The purpose of the **VASCAZEN®-REVEAL** trial was to demonstrate that CVD patients are nutritionally deficient in Omega-3 fatty acids, and through treatment with **VASCAZEN®** such deficiency can be corrected, resulting in the improvement of patient lipid profiles and ultimately reducing CVD risk factors. The trial was a double blind, placebo-controlled study comprised of 110 subjects randomized and stratified by baseline triglyceride levels. The trial analyzed both the placebo (n=54) and **VASCAZEN®** treated (n=56) groups at baseline and after eight weeks of treatment. The primary endpoints were the change in the Omega-Score and Omega-Index, with secondary endpoints including the change in serum triglyceride, lipoprotein cholesterol (VLDL, LDL, HDL, ApoB, and subfractions), and hsCRP. The Omega-Score and Omega-Index are proprietary diagnostic tests that measure circulating blood levels of Omega-3 in individuals. The Omega-Score and Omega-Index are independent measures of risk factors for CVD. The levels correlate with the risk of CVD events; patients with low levels of Omega-3 have a higher incidence of CVD events than patients with high levels of Omega-3.

VASCAZEN® was demonstrated to be highly effective in correcting an Omega-3 deficiency. In eight weeks of treatment a statistically significant ($p < 0.0001$) increase of 121% in the Omega-Score and 112% ($p < 0.0001$) in Omega-Index (the blood levels of EPA, DHA and DPA) was observed in **VASCAZEN®** treated subjects. The **VASCAZEN®-REVEAL** trial confirms Pivotal's Open Label Study results conducted in 2011 that identified >80% of CVD patients as Omega-3 deficient. The **VASCAZEN®** formulation had a profound effect on correcting an Omega-3 deficiency and positive effect on lipid profiles, mainly the reduction of triglycerides and raising HDL in as little as eight weeks of treatment.

Triglyceride Reduction Levels and Secondary Endpoints Exceeded Company Expectations

The median placebo adjusted reduction in triglycerides in the **VASCAZEN®** treatment group was 48%. This reduction was statistically significant ($p < 0.0005$). The median baseline triglyceride levels

were 264.00 mg/dL and 274.50 mg/dL for the patient groups treated with placebo and **VASCAZEN**[®], respectively. The **VASCAZEN**[®] treated group showed VLDL-C reduction of 30% (p=0.0023) and HDL-C increase of 9% (p=0.0069) without significantly affecting LDL-C, ApoB or hsCRP levels. The safety profile of **VASCAZEN**[®] was similar to placebo with no treatment related serious adverse events reported in the trial.

“We are very pleased with the results of the **VASCAZEN**[®]-REVEAL trial,” said Dr. George Jackowski, Chairman and Chief Scientific Officer. “Both primary and secondary endpoints were met, with the evidence supporting the efficacy of **VASCAZEN**[®] in correcting an Omega-3 deficiency and addressing some important CVD risk factors, such as patient lipid profiles. The statistically significant elevation in Omega-3 levels, drop in triglycerides, and the elevation of HDL cholesterol, all in eight weeks, evidences the deficiency is being corrected and patients are seeing results. The positive data from the **VASCAZEN**[®]-REVEAL study show that **VASCAZEN**[®] could be an important therapeutic option for correcting an Omega-3 deficiency, thereby reducing CVD risk factors including high triglycerides in patients who do not meet the current criteria for pharmaceutical treatment targeting high triglycerides.”

The **VASCAZEN**[®]-REVEAL trial is the only trial that addresses an Omega-3 deficiency in cardiovascular patients. “We are happy to see that the trial’s screening results confirm the deficiency levels we saw in our earlier open label study,” says Rachelle MacSweeney, President and COO. “The evidence shows that the Omega-3 deficiency presents in a significant number of CVD patients, representing a large market opportunity for **VASCAZEN**[®] and we look forward to incorporating the data from the study into our current marketing message.”

The **VASCAZEN**[®]-REVEAL trial confirms that Omega-3 deficiency is prevalent in individuals with CVD, and that such a deficiency can be corrected with **VASCAZEN**[®], a 6:1 EPA:DHA Omega-3, resulting in a concomitant and significant placebo-corrected reduction in triglycerides and VLDL, and increase in HDL-C in patients with high triglycerides (200-500mg/dL), without adversely affecting LDL-C.

About the Study

The **VASCAZEN**[®]-REVEAL trial was a randomized, double blind, placebo controlled, multi-center USA based study that enrolled 110 patients. The purpose of the study was to evaluate the effects of **VASCAZEN**[®] in the correction of Omega-3 deficiency in patients with one or more risk factors associated with CVD, and to evaluate **VASCAZEN**[®]’s concomitant effects on cardiovascular risk factors including triglycerides, VLDL cholesterol, LDL cholesterol, and HDL cholesterol among others. The primary efficacy endpoint was the correction of an Omega-3 deficiency, and secondary endpoints included positive effects on lipid profiles, without any adverse events.

Of the 110 patients enrolled > 85% were Omega-3 deficient. The **VASCAZEN**[®]-REVEAL trial is the first to determine dietary levels of Omega-3 in plasma and in red blood cells using the Omega-Score and Omega-Index diagnostics. Improvement after treatment with **VASCAZEN**[®] and the concomitant beneficial effects on CVD risk factors in patients with high triglycerides (200-500mg/dL) was analyzed.

About VASCAZEN

VASCAZEN[®] is a currently available prescription only Medical Food specifically formulated for the dietary management of an Omega-3 deficiency in cardiovascular patients. **VASCAZEN**[®] is a >90% pure Omega-3 with a proprietary 6:1 EPA:DHA fatty acid formulation, protected by a series of both U.S. and foreign patents. **VASCAZEN**[®] is the second to market prescription only Omega-3 therapy available in the U.S. and is available by prescription nationwide.

About Pivotal Therapeutics Inc.

Pivotal Therapeutics is a publicly traded (OTCQX: PVTTF) (CNSX: PVO) specialty pharmaceutical company with a focus on cardiovascular disease and overall health. Pivotal Therapeutics' lead product **VASCAZEN**[®] is a prescription only Medical Food formulated to meet the dietary Omega-3 deficient needs of patients with cardiovascular disease through elevating Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) to levels associated with reduced risk of cardiovascular complications. **OMAZEN**[™] is a prescription grade Omega-3 providing >90% total Omega-3 in each capsule with a unique 6:1 ratio of EPA:DHA. **OMAZEN**[™] is a patented product available for sale and distribution in Canada.

Disclosure Notice

The information contained in this document is as of May 7, 2013. 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. CNSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this information.

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