

News Release

VASCAZEN® POMEGA PHASE IIa TRIAL PROTOCOL CLEARED CLINICAL EVALUATION BY FRENCH FDA

FOR IMMEDIATE RELEASE

December 17, 2014

Woodbridge, Ontario, December 17, 2014 - Pivotal Therapeutics Inc. (OTCQX:PVTF; CSE:PVO), ("Pivotal" or the "Company"), a specialty pharmaceutical company with a focus on Omega-3 therapies for cardiovascular disease (CVD) and overall health, announced that on December 16, 2014 the French FDA in Paris (ANSM: Agence Nationale de la Sécurité du Médicament - French National Agency for Drug Safety) officially cleared the clinical evaluation part of the **VASCAZEN® POMEGA** Phase IIa trial protocol.

The **VASCAZEN® POMEGA** Phase IIa clinical trial is a double-blinded placebo controlled study in over 100 patients scheduled to undergo vascular invasive surgery for carotid endarterectomy at the University Hospital of Strasbourg, France. Patients shall be randomized to receive either Pivotal's uniquely formulated **VASCAZEN®** product or placebo for six consecutive weeks. The composite primary endpoint of the trial consists of histomorphological, biochemical and immunological status of the vascular plaque. The trial is being coordinated and monitored locally by Preventor µTBC GmbH, a German drug safety corporation specialized in pre-clinical and clinical pharmacovigilance, that provides guidance to Pivotal in Europe. More than 4,000 patients are diagnosed with carotid plaque stenosis in France annually.

"Pivotal is privileged to have the opportunity to be working with the French FDA and Preventor on the **VASCAZEN® POMEGA** trial, said Dr. George Jackowski, Pivotal's Founder and Chief Scientific Officer. "With this trial, it opens up **VASCAZEN®**'s formulation as a drug indication in Europe and potentially in the U.S. marketplace.

About VASCAZEN®

VASCAZEN® is currently available in the U.S. as a 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® has been clinically shown to correct an Omega-3 deficiency within eight weeks of treatment with positive concomitant effects on the lipid profiles, mainly a 48% reduction of triglycerides and an increase of HDL without negative impact on the LDL-C lipid profile. **VASCAZEN®**'s results were achieved with a dose of 3 grams of EPA and DHA per day of a prescription grade, high purity, uniquely formulated Omega-3.

About Pivotal Therapeutics Inc.

Pivotal Therapeutics is a publicly traded (OTCQX:PVTF; CSE: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 pharmaceutical grade



Omega-3 providing over 90% pure Omega-3 in each capsule for the maintenance of good health. **OMAZEN®** is a patented product available for sale and distribution in Canada.

Disclosure Notice

The information contained in this document is as of December 17, 2014. 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 CSE 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. The CSE has not reviewed and does not accept responsibility for the adequacy or accuracy of this information.

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