



# News Release

## PIVOTAL THERAPEUTICS RECEIVES FINAL APPROVAL FOR PHASE IIa CLINICAL TRIAL WITH PVT-100

**FOR IMMEDIATE RELEASE**

**January 27, 2015**

**Woodbridge, Ontario, January 27, 2015 – 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 and overall health, announced today that it has received the final and unrestricted authorization from the Agence Nationale de la Sécurité du Médicament - French National Agency for Drug Safety to conduct a Phase IIa clinical trial with its **PVT-100** drug candidate. **PVT-100** uses **VASCAZEN**<sup>®</sup>'s proprietary formulation for the stabilization of vulnerable plaque in patients undergoing carotid endarterectomy, a surgical procedure to remove material accumulated in the arteries to reduce the risk of stroke.

The **VASCAZEN**<sup>®</sup> **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 drug candidate **PVT-100** or a placebo, for six consecutive weeks. The composite primary endpoint of the trial consists of histomorphological, biochemical and immunological status of the vascular plaque.

“This is a significant milestone for Pivotal as our patented formulation moves towards a drug indication in Phase IIa in Europe,” said Dr. George Jackowski, Pivotal’s founder and Chief Scientific Officer. “We look forward to enrolling our first patient in the second quarter of this year.”

### **About VASCAZEN**<sup>®</sup>

**VASCAZEN**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup>'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**<sup>®</sup> 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**<sup>®</sup> is a pharmaceutical grade Omega-3 providing over 90% pure Omega-3 in each capsule for the maintenance of good health.



**OMAZEN**<sup>®</sup> is a patented product available for sale and distribution in Canada. **BeneFishial**<sup>™</sup> is the first product in Pivotal's new nutraceutical product line, which has been specifically designed to be sold in the OTC direct to retail or direct to consumer markets.

## **Disclosure Notice**

*The information contained in this document is as January 27, 2015. 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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