



News Release

FIRST PATIENT ENROLLED IN PIVOTAL'S POMEGA PHASE IIa CLINICAL TRIAL WITH PVT-100

FOR IMMEDIATE RELEASE

June 4, 2015

Woodbridge, Ontario, June 4, 2015 - Pivotal Therapeutics Inc. (OTCQX: PVTTF) (CSE: PVO), a specialty pharmaceutical company with a focus on Omega-3 therapies for cardiovascular disease (CVD) and overall health, announced today the enrollment of the first patient in Pivotal's **POMEGA** Phase IIa clinical trial with **PVT-100**.

The **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.

The trial entitled "*Impact of an optimized Omega 3 formulation on the biochemical and histopathological composition of atheromatous plaques in patients to undergo carotid endarectomy*" is sponsored by the University Hospital of Strasbourg and authorized by the French national supervisory authority ANSM, the equivalent to the U.S. FDA. This trial is coordinated by an interdisciplinary team of six vascular surgeons and twenty health professionals and monitored by the French health authorities via the national Clinical Trial Management System (CTMS). This system supervises all therapeutic clinical trials performed in France. Product packaging, supply and trial logistics including on site quality control/compliance monitoring is performed by German drug safety corporation Preventor μ TBC GmbH.

"We are very excited about the enrollment of the first patient in the **POMEGA** trial," stated Dr. George Jackowski, Co-Founder and Chief Scientific Officer. "Positive results of the trial will allow for new indications for prescription Omega-3 formulations, initiating novel therapeutic regimes beyond treating patients with very high triglycerides."

About Pivotal Therapeutics Inc.

Pivotal Therapeutics is a publicly traded (OTCQX:PVTTF; 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 specially formulated for the dietary management of Omega-3 deficiency in 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 for the professional market. **BeneFishial**[™] 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. The Company's product line is being expanded to include its first drug candidate **PVT-100** and a point of care diagnostic **OmegaSTAT**[™]. **PVT-100** utilizes **VASCAZEN**[®]'s unique formulation for the stabilization of



vulnerable plaque in patients undergoing carotid endarterectomy. **OmegaSTAT™** is a rapid format point-of-care (POC) diagnostic test being developed to measure Omega-3 deficiency.

Disclosure Notice

The information contained in this document is as of June 4, 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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