



News Release

PIVOTAL RECEIVES NOTICE OF ALLOWANCE FOR U.S. PATENT APPLICATION 14/594,095 FOR THE STABILIZATION OF VULNERABLE PLAQUE UTILIZING A COMBINATION OF STATIN AND PVT-100

FOR IMMEDIATE RELEASE

October 8, 2015

Woodbridge, Ontario, October 8, 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 the United States Patent and Trademark Office (“USPTO”) has published notification of a Notice of Allowance for Pivotal’s U.S. Patent Application Serial Number 14/594,095 entitled “Process and Composition For Stabilization of Vulnerable Plaque Utilizing a Combination of a Statin and Omega 3 Fatty Acids.” This notice constitutes allowance of the patent and impending issuance. The issued patent would have a term that expires no earlier than in 2032.

“This patent allowance is the first and only of its kind to date that has claims for an Omega-3 formulation and processes for the stabilization of vulnerable plaque,” stated Dr. George Jackowski, Co-Founder and Chief Scientific Officer.

This allowance is the first in a series of patents surrounding Pivotal’s first drug indication **PVT-100** formulated for the stabilization of vulnerable plaque. The Company is currently enrolling patients for its first targeted indication in patients undergoing carotid endarterectomy. 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 are 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.

“Depending on the outcome of the ongoing Phase IIa clinical trial, a successful outcome as a result of stabilizing vulnerable plaque, will have a profound affect in the future on how cardiovascular patients will be treated for acute cardiovascular events, mainly heart attacks and stroke,” added Dr. George Jackowski.

This application is part of Pivotal’s expanding patent portfolio that protects its unique Omega-3 formulation. The Company has a total of five (5) issued and allowed patents and seven (7) patent applications currently in prosecution in the U.S. The Company is pursuing patent applications related to **VASCAZEN**®’s formulation, composition, combinations with cardiovascular drugs and an Omega-3 fatty acid diagnostic assay in the U.S. and in multiple jurisdictions outside the United States.

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 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 October 8, 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 ability to obtain additional financing on acceptable terms; growth in costs and expenses; ability 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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