



News Release

PIVOTAL THERAPEUTICS ANNOUNCES ISSUANCE OF U.S. PATENT 9,248,138 FOR THE STABILIZATION OF VULNERABLE PLAQUE UTILIZING A COMBINATION OF STATIN AND OMEGA 3 FATTY ACIDS

FOR IMMEDIATE RELEASE

February 2, 2016

Woodbridge, Ontario, February 2, 2016 – Pivotal Therapeutics Inc. (CSE:PVO; OTC PINK:PVTF), (“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”) issued Patent number **9,248,138** entitled “Process and Composition For Stabilization of Vulnerable Plaque Utilizing a Combination of a Statin and Omega 3 Fatty Acids.” The issued patent would have a term that expires no earlier than in 2031.

“This issued patent 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 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.

“A successful outcome of the Phase IIa trial, as a result of stabilizing vulnerable plaque, will have a profound effect in the future on how cardiovascular patients will be treated for the prevention of 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 six (6) patent applications currently in prosecution in the U.S. The Company is pursuing patent applications related to **VASCAZEN**®’s Omega-3 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 (**CSE:PVO; OTC PINK:PVTF**), 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**[™] and **BeneFishial**[™] **Pet** are the first products in Pivotal's new nutraceutical product line, which is specifically designed to be sold in the over-the-counter (OTC) direct-to-retail or direct-to-consumer markets and animal health and nutrition 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 February 2, 2016. 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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Company Contacts:

Kristine DiMatteo
Communications and Public Relations Manager
Phone: 905-856-9797 ext. 231
E-Mail: kdimatteo@pivotaltherapeutics.us