



# News Release

## PIVOTAL RECEIVES NOTICE OF ALLOWANCE FOR U.S. PATENT RELATED TO A KIT FOR THE DIETARY MANAGEMENT OF CARDIOVASCULAR PATIENTS THAT INCLUDES VASCAZEN® AND AN OMEGA-3 FATTY ACID DIAGNOSTIC ASSAY

FOR IMMEDIATE RELEASE

April 1, 2015

Woodbridge, Ontario, April 1, 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 13/584,428 entitled “Omega 3 Fatty Acid for use as a Prescription Medical Food and Omega 3 Fatty Acid Diagnostic Assay for the Dietary Management of Cardiovascular patients with Cardiovascular Disease (CVD) who are Deficient in Blood EPA and DHA Levels.” This notice constitutes allowance of the patent and impending issuance. The issued patent would have a term that expires no earlier than in 2032.

The present invention provides a kit for the dietary management of cardiovascular patients with cardiovascular disease who are deficient in blood Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) levels. This kit includes a diagnostic assay for determining blood levels of EPA, DHA and Docosapentaenoic acid (DPA) and a pharmaceutical grade prescription medical food Omega-3 fatty acid formulation containing about 90% or more Omega-3 fatty acids by weight including a combination of EPA, DPA and DHA in a weight ratio of EPA:DHA of 5.7:1 to 6.3:1. The sum of the EPA, DHA and DPA are about 82% by weight of the total formulation and about 92% of the total Omega-3 fatty acid content of the composition. EPA + DHA are about 80% of the total formulation and about 89% of the total Omega-3 fatty acid content of the composition.

“This is a key patent in our portfolio that surrounds our unique Omega-3 formulation,” said Dr. George Jackowski, Pivotal’s Founder and Chief Scientific Officer. “In fact, in this allowed patent, we were able to obtain separate independent claims to our unique Omega-3 formulation that is the basis of a series of products being commercialized by Pivotal.”

This application is part of Pivotal’s expanding patent portfolio that protects its unique formulation. The Company has a total of four (4) 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 existing obesity and cardiovascular drugs and an Omega-3 fatty acid diagnostic assay in the U.S. and in multiple jurisdictions outside the United States.

### 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**<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.

### **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 April 1, 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.*

- # -

### **Company Contacts:**

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