



# News Release

## PIVOTAL THERAPEUTICS ANNOUNCES ISSUANCE OF U.S. PATENT 9,119,826 FOR A KIT THAT INCLUDES VASCAZEN® AND AN OMEGA-3 FATTY ACID DIAGNOSTIC ASSAY FOR THE DIETARY MANAGEMENT OF CARDIOVASCULAR PATIENTS DEFICIENT IN OMEGA-3

FOR IMMEDIATE RELEASE

September 22, 2015

Woodbridge, Ontario, September 22, 2015 - Pivotal Therapeutics Inc. (OTCQX: PVTF) (CSE: PVO), a specialty pharmaceutical company with a focus on Omega-3 therapies for cardiovascular disease (CVD) and overall health, announced that the U.S. Patent and Trademark office (USPTO) has issued Patent Number **9,119,826** titled "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 patent has terms that expire no earlier than 2032.

"This patent specifically supports **VASCAZEN®**, a prescription only medical food available in the U.S., specifically formulated for the dietary management of an Omega-3 deficiency in cardiovascular patients and includes a diagnostic test that can identify and monitor Omega-3 deficient patients using a rapid format procedure that can be done at the point of care," stated Dr. George Jackowski, Pivotal's Founder and Chief Scientific Officer. Omega-3 deficiency has a significant impact on cardiovascular mortality with 84,000 deaths attributed to Omega-3 deficiency in the U.S. annually which is comparable to 113,000 deaths in the U.S. as a result of high LDL cholesterol levels as reported in the publication "The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors" by researchers at the Harvard School for Public Health (Danaei G et al. 2009)."

The issuance of this patent adds to the Company's expanding patent portfolio regarding its unique Omega-3 formulation, which is now protected by 11 filed and issued patents. The Company is pursuing patent applications related to its 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 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®** 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.

### About VASCAZEN®

**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.

### **About OMAZEN**<sup>®</sup>

**OMAZEN**<sup>®</sup> is Pivotal's second commercial product to market and is available for sale and distribution for the professional over the counter (OTC) market in Canada. **OMAZEN**<sup>®</sup> contains greater than 90% pure, pharmaceutical grade Omega-3 with a unique ratio of EPA to DHA for the maintenance of good health. **OMAZEN**<sup>®</sup>, like all of Pivotal's products, is backed by clinical data and scientific support providing a superior alternative to what is currently available on the market.

### **About BeneFishial**<sup>™</sup>

**BeneFishial**<sup>™</sup> was created as the cornerstone of our new nutraceutical product line, which will include prenatal, children, heart and animal health orientated products. **BeneFishial**<sup>™</sup> was specifically designed as a nutraceutical to be sold in the OTC direct to retail or direct to consumer markets in both the U.S. and in Canada. **BeneFishial**<sup>™</sup> contains the highest content of Omega-3 fatty acids of any other OTC product on the market. It is specifically formulated to give the highest purity, highest anti-inflammatory properties and the best therapeutic effect for a healthy body and mind. It contains the optimal purity, ratio and dose of Omega-3 and is a simple solution to a number of health risk factors.

### **Disclosure Notice**

*The information contained in this document is as of September 22, 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. 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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