

# **News Release**

# PIVOTAL RECEIVES HEALTH CANADA APPROVAL TO EXPAND THE INDICATION OF OMAZEN® TO INCLUDE PRODUCTS WITH CLAIMS TO MAINTAIN AND SUPPORT CARDIOVASCULAR HEALTH AND NORMAL TRIGLYCERIDE LEVELS

### FOR IMMEDIATE RELEASE

**April 27, 2015** 

Woodbridge, Ontario, April 27, 2015 - Pivotal Therapeutics Inc. (OTCQX:PVTTF; 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 it received Health Canada approval to expand the indication of **OMAZEN®**'s product line specifically for cardiovascular health. The Natural and Non-Prescription Health Products Directorate of Health Canada (NNHPD) issued Natural Product Number (NPN) NPN 80060196 with the claim that helps to maintain and support cardiovascular health and NPN 80060197 with the claim helps support and maintain normal serum/blood triglycerides/triacylglycerol levels. These new products contain the same unique formulation and high purity as OMAZEN® and will also be positioned for the professional market such as Wellness Clinics. Cardiac Rehabilitation Clinics, Sports Medicine Clinics and Private Executive Healthcare Clinics.

"This is the first greater than 90% pure Omega-3 fatty acid prescription grade formulation in Canada with a claim to maintain and support triglyceride levels and cardiovascular health," said Dr. George Jackowski, Pivotal's Co-Founder and Chief Scientific Officer. "Physicians to date can only prescribe fenofibrates which can damage the liver. This is the first natural alternative in Canada that is supported by clinical data for cardiovascular patients."

"The approval of Health Canada and the issuance of the NPN's allows consumers to feel assured that the product is safe, effective and of high quality," said Mrs. Rachelle MacSweeney, Pivotal's Co-Founder President and Chief Operating Officer. "As part of the process, companies must provide information about the product including scientific research supporting any health claims, medicinal and non-medicinal ingredients used, product labeling and information about the manufacturing site. This process is among the many steps Pivotal takes to ensure that consumers can feel confident they are truly taking a product that can make a positive difference in their health."

#### **About OMAZEN**

**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 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 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.

#### **Disclosure Notice**

The information contained in this document is as April 27, 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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