News Release

PIVOTAL ANNOUNCES PUBLICATION EVALUATING 171 OVER-THE-COUNTER (OTC) OMEGA-3 NUTRITIONAL SUPPLEMENTS –

50% OF THE OTC PRODUCTS FAILED AT LEAST ONE OF THE OXIDATIVE SAFETY LIMITS

FOR IMMEDIATE RELEASE **November 6, 2015**

Woodbridge, Ontario, November 6, 2015 – Pivotal Therapeutics Inc. (OTCQB: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 the publication of a research article entitled "Oxidation levels of North American over-the-counter *n-3* (omega-3) supplements and the influence of supplement formulation and delivery form on evaluating oxidative safety." The article was authored by Stefan A. Jackowski, Azhar Z. Alvi, Abdur Mirajkar, Zahabia Imani, Yulia Gamalevych, Nisar A. Shaikh and George Jackowski and is now available in the peer-reviewed publication Journal of Nutritional Science with open public access at http://journals.cambridge.org/repo_A99uJU/rER5dac.

"We are extremely excited about this publication because it addresses a growing concern in the safety and efficacy of over-the-counter products," stated Dr. George Jackowski, Pivotal's Co-Founder and Chief Scientific Officer. "The study showed that 50% of the 171 OTC omega-3 products analyzed failed at least one of the oxidative safety limits as proposed by international agencies. The study also suggested that 68% of the products tested have or will exceed the voluntary limits and expose consumers to higher oxidative products well before their dates of expiry. Increased levels of oxidation may dramatically affect the efficacy and safety of the products and counteract their intended benefit. Exposure to oxidation may be additionally detrimental for growing children and adolescents since this is a unique period where rapid changes in growth and development are taking place, therefore the already vigilant industry needs to further enhance safety procedures and regulations in testing the final product being consumed by the general public," added Dr. George Jackowski.

Highlights of the Abstract

- 171 OTC omega-3 polyunsaturated fatty acids (PUFA) nutritional supplements were analyzed against oxidative safety standards.
- 50% of them failed at least one of the voluntary oxidative safety standards.
- Oxidative safety was further investigated to evaluate the contributions of formulation and delivery form.
- Encapsulated, unflavoured fish oil omega-3 PUFA, appear as the safest and readily testable consumer products.
- The research article suggests that present oxidation safety recommendations endorsed by international agencies are applicable to fish oil products only and their scope needs to be extended to all omega-3 PUFA products regardless of delivery form or formulation.

- The research article highly recommends that oxidative safety limits need to be introduced by regulatory bodies to ensure the safety, compliance, testability and efficacy of all omega-3 PUFA nutritional supplements.

Abstract

The aim of the study was to evaluate the oxidation status of North American omega-3 polyunsaturated fatty acids (PUFA) nutritional supplements commercially available in Canada and evaluate the influence of product formulation and delivery form on oxidative safety. A total of 171 North American over-the-counter omega-3 PUFA nutritional supplements were analyzed for oxidation safety. Primary and secondary oxidation and total oxidation (TOTOX) were determined using the American Oil Chemists' Society (AOCS) procedures. Comparisons between supplements' final forms, oil source and omega-3 PUFA concentration quartiles, as measures of product formulations and delivery forms, were compared using ANOVA. Of the products successfully tested, 50% exceeded the voluntary recommended levels for markers of oxidation. Another 18% of products were approaching the limits with 1-3 years before expiration. Encapsulated products without flavor additives had significantly lower secondary and TOTOX levels than bulk oils and flavoured products ($P < 0.05$). Children's products had significantly higher primary, secondary and TOTOX levels compared with all other products ($P < 0.05$). Markers of oxidation did not differ between oil sources ($P < 0.05$), with the exception of krill oil products having higher secondary oxidation levels than plant-based products ($P < 0.05$). Markers of oxidation did not differ between omega-3 PUFA supplement concentration quartiles. Consumers may be at risk of exposure to higher levels of oxidative products. New regulatory mandates need to be introduced to ensure that all omega-3 PUFA products, used as nutritional supplements, regardless of their formulations or delivery form, can be tested for oxidative safety and compliance.

About Pivotal Therapeutics Inc.

Pivotal Therapeutics is a publicly traded **(OTCQB: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 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 is 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 November 6, 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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