# Proteon Therapeutics and Lonza Extend Manufacturing Agreement for Commercial Supply

May 8, 2018

- Partners extend existing contract for manufacture of vonapanitase to 2029 as ongoing Phase 3 trial nears completion
- Lonza Pharma & Biotech successfully scaled up a lab process at their Microbial facility in Visp, Switzerland, providing flexible solutions as Proteon moves toward possible commercialization
- Lonza's experience in products with Breakthrough Therapy Designation provides expert support for these fast paced, challenging projects

BASEL, Switzerland and WALTHAM, Mass., May 08, 2018 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq:PRTO), a company developing novel, first-in-class therapeutics to address the medical needs of patients with kidney and vascular diseases, today announced a long-term contract extension with Lonza Pharma & Biotech for the commercial supply of investigational vonapanitase's active pharmaceutical ingredient (API).

"Proteon and Lonza have had a strong relationship for nearly a decade, and this amendment extends that relationship," said Timothy Noyes, President and Chief Executive Officer of Proteon. "The amendment provides Proteon with access to a top-tier manufacturing site for the long-term commercial supply of investigational vonapanitase after potential FDA approval."

"Lonza's microbial expertise and versatile assets will enable us to anticipate and deliver API for Proteon at this critical phase in the lifecycle of their therapy," said Marc Funk, COO Lonza Pharma & Biotech.

Karen Fallen, VP, Head of Clinical Development and Manufacturing for Lonza, added: "It's always motivating for our teams to support biotechs like Proteon from Phase I studies through to commercialization and to see the impact for patients."

Lonza has manufactured API for Proteon at its microbial manufacturing facility in Visp (CH) since 2009. Initially, a small-scale process was transferred into Lonza's development labs for process optimization and consistency studies. The process was then scaled up to 1,000L scale cGMP manufacture to support Proteon's early clinical studies and potential commercial requirements.

As Proteon worked to complete enrollment in its ongoing Phase 3 clinical trial, PATENCY-2, Lonza supported Proteon with three process validation batches at 1,000L commercial scale, each of which met the intended release criteria. If PATENCY-2 is successful, Proteon expects to include results from these validation runs in a potential Biologics License Application (BLA) filing in the second half of 2019, which Lonza will support.

**About Vonapanitase**
Vonapanitase is an investigational drug intended to improve hemodialysis vascular access outcomes. Vonapanitase is currently being studied in a Phase 3 clinical trial in patients with chronic kidney disease (CKD). It has received Breakthrough Therapy, Fast Track and Orphan Drug designations from the FDA, and Orphan Medicinal Product designation from the European Commission, for hemodialysis vascular access indications. Proteon is also currently conducting a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD).

**About Proteon Therapeutics**
Proteon Therapeutics is committed to improving the health of patients with kidney and vascular diseases through the development of novel, first-in-class therapeutics. Proteon's lead product candidate, vonapanitase, is an investigational drug intended to improve hemodialysis vascular access outcomes. Proteon is evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula. Proteon is also evaluating vonapanitase in a Phase 1 clinical trial in patients with PAD. For more information, please visit www.proteontx.com.

**About Microbial Manufacturing at Lonza Pharma & Biotech**
Recent developments in next generation biotherapeutics including antibody mimetics and novel scaffolds have spurred a renewed interest in microbial protein expression and manufacture technologies. Lonza's proven XS® Microbial Expression Platform combined with more than 30 years of process development and cGMP manufacture expertise make us an ideal partner to successfully support clinical and commercial programs. .More information can be found at: pharma.lonza.com/microbial.

**About Lonza**
Lonza is one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. As an integrated solutions provider, Lonza is boosting its value creation along and beyond the healthcare continuum with a strong focus on patient healthcare, consumer preventive healthcare and consumer's healthy environment.

Lonza harnesses science and technology to create products that support safer and healthier living and that enhance the overall quality of life. With the recent

Capsugel acquisition, Lonza now offers products and services from the custom development and manufacturing of active pharmaceutical ingredients to innovative dosage forms for the pharma and consumer health and nutrition industries.

Benefiting from its regulatory expertise, Lonza is able to transfer its know-how from pharma to hygiene and fast-moving consumer goods all the way to coatings and composites and the preservation and protection of agricultural goods and other natural resources.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 14,500 full-time employees worldwide. The company generated sales of CHF 5.1 billion in 2017 with a CORE EBITDA of CHF 1.3 billion. Further information can be found at www.lonza.com.

**Cautionary Note Regarding Forward-Looking Statements**

This press release contains statements that are, or may be deemed to be, "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding Proteon's product candidate, vonapanitase, and plans for its commercial manufacture. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks relating to: whether data from early nonclinical or clinical studies will be indicative of the data that will be obtained from future clinical trials; whether vonapanitase will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether Proteon can successfully manufacture, commercialize and market its product candidates. These risks and uncertainties are described more fully in Proteon's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission ("SEC") on March 14, 2018, and Proteon's subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as filed with the SEC, particularly in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In light of the significant uncertainties in these forward-looking statements, no person should place undue reliance on these statements or regard these statements as a representation or warranty by the Proteon or any other person that Proteon will achieve its objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this press release represent Proteon's estimates and assumptions only as of the date of this press release and, except as required by law, Proteon undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this press release.

**Additional Information and Disclaimer**
Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited ("SGX-ST"). Lonza Group Ltd is not subject to the SGX-ST's continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

Lonza Contact Details
**Constance Ward**, Head External Communications
Lonza Group Ltd
Tel +41 61 316 8840
constance.ward@lonza.com

**Sanna Fowler**, Assistant Director Public Relations
Lonza Pharma & Biotech
Tel +41 79 539 0615
sanna.fowler@lonza.com

**Proteon Contact Details**
***Investor Contact***
George Eldridge, Proteon Therapeutics, Senior Vice President and Chief Financial Officer
781-890-0102
geldridge@proteontherapeutics.com

***Media Contact***
Ann Stanesa, Ten Bridge Communications
617-230-0347
proteon@tenbridgecommunications.com

Primary Logo

Source: Proteon Therapeutics, Inc.