



United Therapeutics And XVIVO Perfusion Announce Collaboration To Reduce Organ Shortage Through Expansion Of Organ Evaluation Service

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SILVER SPRING, Md. and ENGLEWOOD, Colo., June 12, 2018 /PRNewswire/ -- United Therapeutics Corporation (Nasdaq: UTHR) and XVIVO Perfusion, Inc., a subsidiary of XVIVO Perfusion AB (STO: XVIVO), today announced that the use of XVIVO's ex-vivo lung perfusion (EVLP) technology will be incorporated into the Silver Spring, Maryland laboratory of Lung Bioengineering Inc., a subsidiary of United Therapeutics' public benefit corporation subsidiary Lung Biotechnology PBC.

"I am excited about trying to make more life-saving use of donated lungs via XVIVO Perfusion's pioneering technology," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics.

"United Therapeutics' impressive history of developing and delivering innovative and effective therapies for severe lung diseases makes them the ideal partner for XVIVO Perfusion in our quest to prevent mortality due to organ shortages," said Dr. Magnus Nilsson, Chief Executive Officer of XVIVO Perfusion.

Lung Bioengineering has agreed to purchase multiple XVIVO Perfusion System (XPS™) machines from XVIVO Perfusion for use in its Silver Spring EVLP laboratory, while XVIVO Perfusion agreed to provide training and supplies for use of the machines to re-evaluate donated lungs that have initially been deemed unsuitable for transplant directly following explant from the donor. In addition, Lung Bioengineering and XVIVO Perfusion agreed to cooperate and collaborate in promoting the use of EVLP services that could increase the supply of transplantable lungs to address needless patient deaths on the transplant waitlist.

About XPS

XPS™ is an integrated system that provides clinicians with the flexibility to evaluate lungs before transplantation by means of a standardized and simplified procedure. The XPS System with STEEN Solution™ allows marginal quality lungs that initially failed to meet standard of care transplant criteria to be perfused and ventilated at normothermic conditions, thus providing an opportunity for surgeons to reassess transplant suitability. XPS and STEEN Solution are used worldwide with good clinical results. The XPS and STEEN Solution have already been CE-marked and thus approved for sales on the European market, and are also approved for sales in Canada and Australia.

In May 2018, XVIVO Perfusion submitted a premarket approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the XPS with STEEN Solution. The NOVEL Extension Clinical trial, which completed enrollment in 2017, constitutes the basis of the company's PMA. The NOVEL Extension study, which completed enrollment in June 2017, involves follow-up of the patients for up to one year. XVIVO Perfusion's PAS (Post Approval Study) required by the FDA for all approvals includes a total of 126+126 patients that will be followed for three years. The inclusion of all patients for the PAS was completed in late 2017.

In March 2014, an FDA Advisory Panel voted unanimously 10-0 that the XPS™ System with STEEN Solution met the requirements for Humanitarian Device Exemption (HDE) approval by proving safety. In August 2014, XVIVO Perfusion received HDE approval from the FDA for the XPS with STEEN Solution for use in flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the ex-vivo function of the lungs can be reassessed for transplantation. HDE approval entails certain restrictions, including a limitation such that no more than 8,000 patients may be treated per year under HDE approval and that separate institutional review board approval may be required for treatment. Upon approval, a PMA would no longer entail any such restrictions.

About United Therapeutics

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions. [uthr-g]

About Lung Bioengineering

Lung Bioengineering is part of United Therapeutics' wholly-owned Lung Biotechnology PBC public benefit subsidiary, which is chartered with the express purpose "to address the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply." Lung Bioengineering owns and operates a laboratory in Silver Spring, Maryland, dedicated to performing centralized ex-vivo lung perfusion procedures designed to provide extended preservation and assessment of lungs otherwise deemed unsuitable for transplant. Website: www.lungbioengineering.com.

About XVIVO Perfusion

XVIVO Perfusion AB is a medical technology company which develops solutions and systems for assessing and preserving organs outside the body and for selecting usable organs and maintaining them in optimal condition pending transplantation. The company is headquartered in Gothenburg, Sweden, and has one office in Lund, Sweden and one office in Denver, USA. The XVIVO share is listed on Nasdaq Stockholm and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com. XVIVO Perfusion AB (publ), Box 53015, SE-400 14 Göteborg. Corporate identity number 556561-0424. Tel: 46 31 788 21 50. Fax: 46 31 788 21 69. E-mail: info@xvivoperfusion.com. Website: www.xvivoperfusion.com

Forward-looking Statements

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements regarding the use of XPS with STEEN Solution to perform services to increase the supply of transplantable lungs, and statements regarding the pending PMA for the XPS with STEEN Solution. These forward-looking statements are subject to certain risks and uncertainties, such as those described in United Therapeutics' periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results. Such forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of June 12, 2018, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason.

XPS and STEEN Solution are trademarks of XVIVO Perfusion, Inc.

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SOURCE United Therapeutics Corporation; XVIVO Perfusion

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