United Therapeutics Announces FDA Approval Of XPS™ And Steen Solution™ Used To Perform Centralized Ex-Vivo Lung Perfusion Services

April 29, 2019

SILVER SPRING, Md., April 29, 2019 /PRNewswire/ -- United Therapeutics Corporation (Nasdaq: UTHR) today announced that its collaborator, XVIVO Perfusion, Inc., a subsidiary of XVIVO Perfusion AB (STO: XVIVO), has received Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) for the products XPS™ and STEEN Solution™. This approval means that STEEN Solution, XPS and the accompanying single-use articles are the only medical device products that are approved in the United States for ex-vivo lung perfusion (EVLP) of initially unacceptable donated lungs at body temperature.

In June 2018, United Therapeutics and XVIVO Perfusion announced a collaboration agreement to incorporate the use of XPS™ and STEEN Solution™ into the Silver Spring, Maryland laboratory of Lung Bioengineering Inc., a subsidiary of United Therapeutics' public benefit corporation Lung Biotechnology PBC. Since then, Lung Bioengineering has used the XPS™ technology to offer centralized EVLP to transplant centers on a fee-for-service basis, in order to increase the supply of transplantable lungs to address needless patient deaths on the transplant waitlist.

"We are proud to be XVIVO Perfusion's partner in offering unique centralized EVLP services to expand the supply of transplantable lungs," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "We are grateful to the FDA for approving this technology that enables otherwise discarded lungs, which would be unable to be used in furtherance of their donors' generous intent, to instead be frequently restored to transplantable and hence life-saving condition. I feel it is a miracle of biotechnology that will benefit thousands of patients who die needlessly awaiting transplant."

Initially, XPS™ was marketed under a Humanitarian Device Exemption (HDE) granted by FDA to XVIVO Perfusion, which permitted the use of XPS™ with STEEN Solution™ for 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 entailed 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. With PMA approval, these restrictions no longer apply.

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™ 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 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 PMA application to the 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. The FDA approved XVIVO Perfusion's PMA application on April 26, 2019.

About United Therapeutics

United Therapeutics Corporation focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture and our bioinformatics leadership. We also believe that our determination to be responsible citizens – having a positive impact on patients, the environment and society – will sustain our success in the long term.

Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are focused on addressing 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 Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company. [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.

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, the ability of our business model to create value, our ability to sustain long-term success, and our organ transplantation research and development programs. 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 April 29, 2019, 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.

View original content:http://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-of-xps-and-steen-solution-used-to-perform-centralized-ex-vivo-lung-perfusion-services-300839492.html

SOURCE United Therapeutics Corporation

James Edgemond, Phone: (301) 608-9292, E-mail: jedgemond@unither.com