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AirXpanders

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AirXpanders presents successful XPAND pivotal trial data at world's largest gathering of plastic surgeons

Highlights

- **AirXpanders' successful XPAND pivotal trial data presented at the American Society of Plastic Surgeons (ASPS) Meeting on October 18, 2015 (US time)**
- **ASPS is the world's largest specialty plastic surgery organization with >7,000 members comprising 94% of all board-certified plastic surgeons in the US**
- **Primary endpoint of study successfully achieved, demonstrates that the AeroForm tissue expanders is a safe and effective alternative to saline tissue expanders**
- **AeroForm reduces the time to expansion – average of 21 days for AeroForm group vs 46 days for saline group**
- **98% of patients found the AeroForm device easy to use and convenient**

Palo Alto, CA, United States – AirXpanders Inc (ASX: AXP) a company developing novel tissue expansion technology for women undergoing breast reconstruction after mastectomy, presented the results of its US IDE pivotal trial (XPAND) at the annual American Society of Plastic Surgery meeting, currently taking place in Boston.

As previously announced on August 25, 2015 the study successfully met the primary endpoint demonstrating that the AeroForm tissue expander is a safe and effective method of expansion as an alternative to saline tissue expansion, to successfully expand the tissue and exchange to permanent breast implants. The positive outcome of this study is a major milestone for the company and the basis on which the company is seeking FDA clearance of the device.

A total of 150 women, ages 18-70 were treated at 17 US sites, randomized to the investigational or saline control groups, and underwent immediate or delayed placement of the tissue expanders. In the 98 women receiving the AeroForm expander, expansion was performed with gradual incremental dosing up to 30 cc/day. The 52 women in the saline control group received the standard course of percutaneous injections of saline. Following complete expansion, both groups went on to the final stage of reconstruction: exchange of the expander and placement of a permanent breast implant.

Treatment success in this trial was defined as successful expansion and exchange to permanent implant. In accordance with the trial objective in this non-inferiority trial, the treatment success rate, excluding non-device related failures, was statistically similar between both groups, while the safety profile of both devices was also similar. Furthermore, the time to complete the expansion and reconstruction process was statistically significantly shorter in the AeroForm group, due to the gradual, patient-controlled method of expansion. The mean days to complete expansion in the AeroForm group 21 days compared to 46 days for the saline group. Ease of use and convenience was measured in the AeroForm group, and 98% of subjects found the device easy to use and convenient.

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The data was presented at ASPS by Dr. Jeffrey Ascherman, Chief of the Division of Plastic Surgery at Columbia University, New York, NY and Principal Investigator for the XPAND pivotal trial.

Dr. Ascherman's abstract entitled *AeroForm Vs Saline Tissue Expansion in Breast Reconstruction: A Prospective Multi-Center Randomized Controlled Clinical Study* was presented in a key breast scientific session at ASPS, which is the annual meeting of the largest specialty plastic surgery organization in the world, with more than 7,000 members and representing 94% of American Board of Plastic Surgery certified surgeons.

Dr. Jeffery Ascherman stated, "The AeroForm has provided the patients in this trial with a faster and more convenient form of tissue expansion versus saline devices.

"A hidden benefit of this device is the fact that the patient can play an active role in recovering her body after breast cancer. My patients have thoroughly enjoyed this role and I am confident that this will appeal to many women across the US and around the world when widely available."

Mr Scott Dodson, President and Chief Executive Officer of AirXpanders said, "The excellent results from the XPAND pivotal trial validate that the AeroForm expander is a safe and effective alternative treatment option for the many women undergoing mastectomy and breast reconstruction.

"We believe women will be pleased to have the choice to control their expansion in a more convenient and faster way, during their difficult road to breast reconstruction. We have already submitted the pivotal study results to the FDA under the 510(k) clearance process so as to make this device available to all women who are considering breast reconstruction following their mastectomy."

The AeroForm device is CE Marked and TGA approved for sale in Australia.

The goal of reconstructive breast surgery is to recreate symmetrical natural shaped breasts after the devastating effects of mastectomy. Recent statistics indicate than approximately only 40% of women complete breast reconstruction after mastectomy due to fear of a lengthy and painful process, with multiple procedures and trips to their doctors' office. AeroForm, a carbon-dioxide filled, injection free remote-controlled tissue expander is an alternative method of tissue expansion, enabling women to control the rate of expansion which can make the process easier, more comfortable and has been shown to shorten the time to expand and complete the reconstruction process.

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About AirXpanders:

Founded in 2005, AirXpanders is a medical devices company focused on the design, manufacture, sale and distribution of its AeroForm® tissue expander used in patients undergoing breast reconstruction following mastectomy. It considers that its AeroForm® device is the best innovation in expander technology in 50 years. AeroForm® uses controlled delivery of small amounts of gas (CO_2) to achieve tissue expansion prior to the placement of a permanent breast implant. AeroForm® successfully eliminates the need for needle-based expansion required for

traditional saline tissue expanders and provides a faster, less painful and less stressful breast reconstruction journey. The Company has CE Mark and TGA approval for AeroForm® and is fully reimbursed under Australian Medicare. To date, AeroForm® has been successfully implanted in over 400 patients worldwide. AirXpanders devices are not cleared or approved for use in the United States and are considered for investigational use only. AirXpanders is cleared for commercialization in Europe and in Australia.

For more information, refer to the Company's website at www.airxpanders.com.

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