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CONTACTS:
Eileen Gardner, RN
Augmenix
781-902-1625
egardner@augmenix.com

Augmenix Announces Positive SpaceOAR® Clinical Trial Results Demonstrating Superior Outcomes at 3-Years

Application of SpaceOAR hydrogel results in lower long-term rectal injury and higher patient quality of life scores

WALTHAM, Mass.—September 27, 2016— Today Augmenix, Inc. (http://www.spaceoar.com/), a medical technology company that develops, manufactures, and sells proprietary absorbable hydrogels that separate and protect organs at risk during prostate radiotherapy, announced the 3-year results from the SpaceOAR System Prostate Cancer US Pivotal Clinical Trial. These results were presented at the 2016 American Society for Radiation Oncology Annual Meeting in Boston, MA as a Late Breaking Abstract, an honor reserved for highly significant and timely findings in clinical oncology, radiobiology or medical physics. Entitled “Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial”, the study results presented by Daniel Hamstra, MD, PhD, a radiation oncologist at Texas Oncology in Irving, TX demonstrated significantly lower rectal toxicity and higher patient quality of life (QOL) scores when the SpaceOAR System was applied prior to radiotherapy as compared to the trial control patients.

The leading side effects of prostate cancer radiotherapy are collectively known as “rectal toxicity” (diarrhea, rectal bleeding, urgency, pain, etc.), which results from unintended radiation injury to the rectum (the Organ At Risk, OAR). These complications can last for years, significantly impacting QOL. The SpaceOAR System was developed to push the rectum away from the high dose region during treatment, and then to be completely absorbed by the body after radiotherapy is complete.

The prospective, randomized, multi-center, patient-blinded clinical trial evaluated rectal and urinary toxicity and QOL impact on prostate radiotherapy patients treated either with SpaceOAR hydrogel, or with no hydrogel (Controls). Previously published initial study results demonstrated spacer safety, and a significant 74% reduction in the volume of rectum receiving 70 Gray radiation at 15 months. Presented today were the patient results three years after the start of prostate radiotherapy.

Following radiotherapy through 3 years no SpaceOAR patients (0%) experienced grade 2 or worse late rectal toxicity, compared to 5.7% in the Control patients (p=0.012). Additionally, at 3 years the average SpaceOAR patient bowel QOL was slightly better than before radiotherapy (+0.48 points), while the Control patients QOL had significantly declined (-5.3 points, p=0.05). The percent of men with significant 10+ declines in bowel QOL at 3 years was 20.5% and 5.4% in the Control and SpaceOAR groups (p=0.02), respectively. Unexpectedly, the SpaceOAR patients also showed benefits in urinary complications and QOL, relative to Controls. In the three years after radiotherapy, grade 1 urinary
incontinence was experienced in 19.6% and 4.3% of the Control and SpaceOAR patients, respectively (p=0.003). Additionally, like bowel QOL, at 3 years the average SpaceOAR patient urinary QOL was slightly better than before radiotherapy (+0.6 points), while the Control patient QOL had declined (-3.3 points, p=0.05).

“The low level of rectum radiation dose seen in the men who received the spacer in this trial is unprecedented, and it is great to see that the spacer rectum protection is resulting in long-term patient benefits,” said Dr. Hamstra. “The idea that three years after treatment patients can be having the same bowel and urinary QOL is wonderful. Essentially patients can complete their treatment and be confident that life can return to normal.”

“Patient quality of life is the new standard for long-term outcomes. This is the first study ever, showing that prostate radiotherapy patients can complete their treatment, and then get their lives back,” said John Pedersen, Augmenix CEO. “Further, this validation of the spacer concept supports our strategy to improve radiotherapy procedures all over the body.”

The Augmenix Products
Using a minimally invasive procedure, SpaceOAR System is injected as a liquid into the space between the prostate and rectum where it expands the space and then solidifies into a soft hydrogel. The hydrogel remains stable for three months while protecting the rectum during radiotherapy, and then liquefies and is completely absorbed. The SpaceOAR System is FDA Cleared, CE marked and is also approved in Australia and Canada. Augmenix also markets TraceIT® Hydrogel, the world’s first absorbable hydrogel tissue marker with CT, MRI and ultrasound visibility. TraceIT Hydrogel is FDA cleared as an absorbable tissue marker, and is CE marked and approved in Australia as an absorbable tissue marker and spacer. See the Instructions for Use for complete information on potential risks, warnings and precautions.

About Augmenix, Inc.
Augmenix, Inc. is a privately held company based in the Boston area focused on the development and commercialization of radiation oncology products using its proprietary hydrogel technology. The company was founded by Incept LLC in 2008 and is funded by several leading venture capital groups. More information about Augmenix can be found at http://www.Augmenix.com.

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