

Media Release

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FOR IMMEDIATE RELEASE

Augmenix Receives CE Mark Approval for TracelT[®] Fiducial Marker and TracelT[®] Gel System

Waltham, Massachusetts November 5, 2013:

Augmenix, Inc. today announced that it has received European commercial approval for both TracelT Fiducial Marker and TracelT Gel System, absorbable markers visible under CT, MR, cone beam and ultrasound imaging modalities. The TracelT Fiducial Marker (1 mL) is indicated as an absorbable fiducial marker, while the TracelT Gel System (3 and 10 mL) is indicated as a soft tissue marker as well as to create space within soft tissue to guide radiotherapy. These CE Mark approvals follow the earlier commercial release of TracelT Tissue Marker (1 mL) in the United States. TracelT hydrogel is injected via fine needles or cannulae, remains visible for at least 3 months, then liquefies and is absorbed by the body over time.

Because TracelT hydrogel is soft and lacks the hard edges of metal fiducial marks, it is able to mark structures like the bladder wall where conventional markers tend to migrate. “Typical markers migrate from the bladder wall due to continuous stretching and contraction. TracelT hydrogel appears to provide a stable, visible mark, allowing for more accurate radiotherapy planning and treatment,” said Karim Chamie MD, Assistant Professor of Urology, UCLA Medical Center, Santa Monica, CA. The fine needle delivery

and lack of artifact also make it well suited for marking liver tumors in patients scheduled to undergo liver radiotherapy. “TracelT hydrogel not only improves visibility through reduced artifact on both fan-beam and cone-beam CT images, but also allows for the delivery of multiple marks through a single smaller needle, potentially reducing pain and the risk of bleeding”, said Drew Moghanaki MD, MPH, Director of Clinical Research, Hunter Holmes McGuire Veterans Affairs Hospital, Richmond, VA.

With its larger syringe volumes, TracelT Gel System is well suited to mark tissue margins following surgery, in procedures where postoperative radiotherapy is anticipated. The breast lumpectomy site is often difficult to see in postoperative imaging, necessitating irradiation of the entire breast. A material that improves breast cavity visibility may enable irradiation targeted to the resection site, thus reducing irradiation to healthy breast tissue, and to the lungs and heart.

The TracelT hydrogel family of products including TracelT Fiducial Marker, TracelT Gel System, and TracelT Tissue Marker are the first absorbable hydrogels designed to mark tissues with CT, MR, cone beam and ultrasound visibility.

“At Augmenix, we are proud to introduce advanced hydrogel products that improve outcomes of radiotherapy by improving guidance to target organs and minimizing damage to adjacent organs. We hope that with these new markers radiotherapy may become an increasingly viable option to treat cancers of the bladder, liver and cervix and expand the market for radiotherapy overall while improving patient care and reducing healthcare costs”, said Amar Sawhney, PhD, CEO of Augmenix.

About Augmenix, Inc. (<http://www.augmenix.com>): Augmenix is a privately held company based in Waltham, MA, focused on the development and commercialization of products that enhance the outcomes and targeting of radiotherapy using its proprietary hydrogel

technology. In addition to TracelT hydrogel, Augmenix has developed SpaceOAR® System, an absorbable hydrogel spacer that reduces radiation injury to the rectal wall in men undergoing prostate radiotherapy. The company was founded in 2008. ###