

**FOR IMMEDIATE RELEASE**

**Pioneering Trial Combining Focused Ultrasound and Immunotherapy for Breast Cancer Begins at University of Virginia**

**Charlottesville, VA – October 24, 2017** – For the first time, focused ultrasound is being used in combination with a cancer immunotherapy drug. In a clinical trial for patients with metastatic breast cancer, non-invasive focused ultrasound therapy is being used to ablate (or destroy) a portion of the primary tumor or metastatic tumors in conjunction with the cancer immunotherapy drug pembrolizumab (Keytruda®). The first patient was treated October 20.

The clinical trial is taking place at the University of Virginia Health System and is led by Patrick Dillon, MD, Associate Professor of Hematology and Oncology, and David Brenin, MD, FACS, Associate Professor of Surgery and Chief of Breast Surgery. “The immune system does not recognize most breast cancers as invading or foreign cells, so the body does not mount an immune response against it,” said Dr. Brenin. “Focused ultrasound induces a local immune response and may have the ability to change that paradigm, enabling a medication like Keytruda to make a difference.”

Preclinical studies suggest that focused ultrasound can “unmask” breast cancer cells, making them visible to the immune system. The hypothesis is that application of focused ultrasound to the tumor creates a local immune response that draws anti-cancer immune cells to the area. Keytruda could then prevent the tumor cells from deactivating the immune cells, allowing the immune cells to continue killing cancerous cells.

The highly accurate focused ultrasound treatment is being delivered using Theraclion’s [EchoPulse system](#) targeting up to 50% of the breast tumor. Fifteen women will be enrolled in the study; patients will be randomized to receive their first dose of Keytruda either prior to or following focused ultrasound treatment.

Dr. Dillon said, “Currently, women with metastatic breast cancer have to endure lifelong treatments such as chemotherapy or anti-estrogen therapy that impart toxicity. We hope that this study will help advance the application of immune therapies as we aim to create more durable responses in women with breast cancer.”

Funding for the trial was provided by the Focused Ultrasound Foundation and the Commonwealth of Virginia. “Cancer immunotherapy has emerged in recent years as one of the most promising areas of medicine. One central initiative of our Foundation is dedicated to exploring how focused ultrasound can enhance its effects even further, for more patients,” said chairman Neal F. Kassell, MD. “This is the first time these therapies have been approved by the FDA to be used in combination in patients, and we are proud to support this innovative trial.”

[Keytruda](#) is not FDA approved for the treatment of breast cancer and is considered investigational for the purposes of this study.

## **Additional Resources**

[Dr. Brenin's webinar](#) (hosted by Theraclion)

[Clinical Trials official page](#)

[Additional coverage at MedicalPhysicsWeb](#)

Patients or physicians who would like more information on this research study should contact:

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## **About the University of Virginia Cancer Center**

UVA Cancer Center is accredited by the Commission on Cancer and is one of 69 National Cancer Institute (NCI) designated cancer centers in the U.S. for its work in cancer research, prevention, detection and treatment. UVA Cancer Center provides comprehensive, world-class cancer treatment in an environment of caring for patients across Virginia, led by doctors who have been honored by publications such as Best Doctors in America® and America's Top Doctors®.

## **About the Focused Ultrasound Foundation**

The Focused Ultrasound Foundation was created to improve the lives of millions of people worldwide by accelerating the development of focused ultrasound, an early-stage noninvasive therapeutic technology with the potential to transform the treatment of many medical disorders. The Foundation is dedicated to ensuring that focused ultrasound finds its place as a mainstream therapy within years, not decades, and works to fund research, foster collaboration, and build awareness among patients and professionals. Since its establishment in 2006, it has become the largest non-governmental source of funding for focused ultrasound research. More information can be found at [www.fusfoundation.org](http://www.fusfoundation.org).

## **About Theraclion**

Theraclion is a French company specializing in high-tech medical equipment using therapeutic ultrasound. Drawing on leading-edge technologies, Theraclion has designed and manufactured an innovative solution for echotherapy, the Echopulse®, allowing non-invasive tumor treatment through ultrasound-guided high-intensity focused ultrasound. EchoPulse is designed to non-invasively ablate breast tumors using real time ultrasound guidance. Although it is not yet approved by the US Food and Drug Administration, the system received the European CE Mark in 2012, where it is used to treat breast fibroadenomas, thyroid nodules, and other conditions. Based in Malakoff, near Paris, France, Theraclion has brought together a team of 35 people, 50% of whom are dedicated to R&D and clinical trials. For more information, please visit Theraclion's website: [www.theraclion.com](http://www.theraclion.com).

## **About Focused Ultrasound**

Multiple intersecting beams of ultrasound are directed and concentrated on a target; much like a magnifying glass can focus beams of light on a single point to burn a hole in a leaf. Where each individual beam passes through the tissue, there is no effect. But, at the focal point, the beams of ultrasound energy can produce many important biological effects. Today, focused ultrasound is approved in the United States to treat essential tremor, uterine fibroids, and the prostate, as well as reduce pain from bone metastases. The technology is also being studied for more than 90 other diseases, including Parkinson's, Alzheimer's, hypertension, and tumors of the brain, liver, breast, and pancreas. Focused ultrasound has certain attributes that create the potential for a unique role in cancer immunotherapy when compared to the other modalities, and several preclinical and clinical studies have demonstrated that FUS can elicit an immune response. [Read more >](#)

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