Cytotron® granted 'Breakthrough Device Designation' by U.S. FDA for treatment of breast, liver, and pancreatic cancers

GAITHERSBURG, MD, - October 30, 2019 - The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) granted Shreis Scalene Sciences (Shreis), in Gaithersburg, MD, 'Breakthrough Device Designation' for the CYTOTRON® - a CE marked, whole-body therapeutic medical device. "We are confident that the FDA will continue to interact with Shreis under the premises of the recent guidance (Breakthrough Devices Program), to enable the marketing submission, with the clinical datasets needed to support it," said Prof. Meena Augustus, Co-Founder CEO & CSO of Shreis. The company's designation request stated that "The Cytotron® is intended to be used to cause degeneration of uncontrolled growth of tissues. It is indicated for treating protein-linked, abnormally regenerating disorders such as neoplastic disease, by selectively targeting and enabling tissue apoptosis, allowing extended progression-free survival, with pain relief, palliation, improved quality and dignity of life. It is indicated for the treatment of solid tumors of the breast, liver, and pancreas."

Dr. Rajah Vijay Kumar D.Sc., Inventor of the Cytotron® and Shreis' technology partner, at Scalene Cybernetics Ltd (SCL), and the Scalene Center for Advanced Research & Development (S-CARD), located in Bengaluru, India, said "The clinical trial with this non-invasive, tissue engineering platform technology called Quantum Magnetic Resonance Therapy (QMRT®) could eventually help to establish the Cytotron® as an integral adjunct to existing standards of care in the cancer armamentarium."(Cytotron® Publication, 2016)

"We are very encouraged by the breakthrough designation that will expedite review of an Investigational Device Exemption and future marketing application by the FDA " said Rayol John Augustus Ph.D., Founder-President and COO of SSS-LLC. The diligent support of Dr. R.V. Kumar D.Sc., the dedicated efforts of Emergo by UL based in Austin, Texas, the

Shreis' regulatory team, the staff of SCL and S-CARD, helped ensure a favorable decision by the FDA.

Shreis, while actively pursuing collaborations for clinical trials in the current proposed indications for use, intend to also submit a request for Breakthrough designation in other solid tumors such as adult and pediatric brain tumors, lung cancer, and other life-limiting diseases.

About Shreis Scalene Sciences LLC

Shreis Scalene Sciences LLC is one of three small medical device businesses of the Shreis Scalene Group, in Montgomery County, MD. Together with the Inventor and Technology partner, Dr. Rajah Vijay Kumar, Shreis Scalene Sciences LLC is bringing to the North and South American market, including Mexico and the Caribbean, non-interventional, novel, therapeutic whole-body, medical devices for degeneration (cancer) and regeneration (musculoskeletal disorders), of human tissue. The mission of Shreis is to introduce this leading-edge platform technology that will impact the survivorship experience and bring safer, patient-centric, affordable treatments to pediatric and adult populations globally.

For more information on the Cytotron® and other Shreis Scalene Group's portfolio of therapeutic and diagnostic medical devices, please visit www.shreis.com (temporarily under revision).

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