

## **NEWS RELEASE**

## IZOTROPIC BEGINS FDA APPROVAL PROCESS

**VANCOUVER, BC – May 25, 2020 – Izotropic Corporation** ("**Izotropic**" or the "**Company**") (CSE: IZO) (OTC US: IZOZF) (FSE: 1R3) is pleased to announce it has engaged company advisor and FDA Consultant, <u>Anita Nosratieh Ph.D.</u>, to develop and manage the Company's application for FDA medical device approval of its dedicated Breast CT Imaging System.

The first stage towards FDA approval is focused on developing a detailed pre-submission strategy and application, which will be managed by Nosratieh. Her extensive experience includes a position as a lead reviewer at the FDA in the approval process of breast cancer screening and diagnostic devices. The pre-submission meeting provides the opportunity to open a dialogue and obtain FDA feedback prior to the actual submission for medical device approval, resulting in a smoother and more efficient approval process which may expedite patient access to breast CT. Tasks associated with the application include finalizing product and indication for use statements, device labelling terms, and clinical and validation study designs to verify future breast CT marketing claims.

The Company expects the development and submission of the application for the presubmission meeting to be completed within 8-10 weeks. An interactive period of clarifying questions may then be entered into, resulting in a formal written response from the FDA. The typical timeline for the formal response is 90 calendar days. Once the formal written response is received, the Company can schedule the pre-submission meeting.

Additionally, Nosratieh will develop a strategy and present breast CT to the FDA's <u>Center for Devices & Radiological Health Payor Communication Task Force</u>, a program that facilitates "medical device sponsors to obtain payor input on clinical trial design or other plans for gathering clinical evidence needed to support positive coverage decisions."

The Company will continue to announce updates to keep its shareholders informed as to its progress and timelines towards the pre-submission meeting, FDA approval processes and US payor adoption of its <u>Breast CT Imaging System.</u>

ON BEHALF OF THE BOARD

## Robert Thast Chief Executive Officer

## About Izotropic Corp.

Izotropic Corporation and its wholly owned U.S. operating subsidiary, Izotropic Imaging Corp. have been established to commercialize the next generation of breast imaging technology for early diagnosis of breast cancer. The Izotropic Breast CT Imaging System produces high resolution breast images in 3D. A single 10 second breast CT scan acquires approximately 500 images, without painful breast compression, providing radiologists with fully 3D viewing of the scanned breast. Mammography scanning requires compression of the breast between 2 imaging plates, resulting in 2D images.

The Company has the exclusive worldwide license from the University of California, Davis (UC Davis) to commercialize the technology developed by principal founder and Company director Dr. John M. Boone and researchers at UC Davis. The license includes all intellectual property, trade secrets, patents and patent-pending applications that are the foundation of the Company's breast CT imaging platform.

Approximately \$20 million in research funding and over 15 years of research and development have been invested in developing this groundbreaking breast CT imaging technology. Research includes a current, ongoing \$2.9M U.S. clinical trial at UC Davis Medical Center.

The Company founders believe that this technology will be a disruptive entry to the market, overcoming many of the challenges faced by existing breast imaging modalities.

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