March 25, 2025

Izotropic Completes Pre-Submission Meeting with FDA for Breast Cancer Screening Indication

- FDA meeting facilitated positive collaborative exchange -

- Key topics included the clinical study protocol synopsis, the benefits versus risks of contrast-enhancement, and the management of breast cancers found on IzoView Breast CT that are not visible on digital breast tomosynthesis -

- Izotropic to submit meeting minutes to the FDA prior to more detailed disclosure -

VANCOUVER and SACRAMENTO, March 25, 2025, Izotropic Corporation (CSE: **IZO**) (OTCQB: **IZOZF**) (FSE: **1R3**) ("**Izotropic**" or the "**Company**"), a medical device company commercializing imaging-based products utilizing innovative and emerging technologies for the more accurate screening, diagnoses, and treatment of breast cancers, is pleased to announce that it completed its pre-submission meeting with the U.S. Food and Drug Administration ("**FDA**") as scheduled on March 20, 2025.

The purpose of the meeting was to discuss Izotropic's recent pre-submission filing and advance the regulatory strategy for its IzoView Breast CT Imaging System. Participants included Izotropic's executive leadership, technical and engineering teams, medical advisors, FDA and statistical consultants, and legal counsel, alongside FDA representatives. The meeting discussion facilitated a collaborative exchange with the FDA, allowing the Company to address the agency's questions and considerations while aligning on expectations for the indication for use and overall clinical study.

Key topics included the overall protocol synopsis, cumulative radiation dose, study patient populations, the number and types of participating clinical study sites, and detailed discussions surrounding contrast agent usage. Specific focus was given to the benefits of contrast-enhanced breast CT in improving breast cancer detection rates in patients with dense breast tissue balanced against the associated risks of additional radiation and iodinated contrast agents. The Company and the FDA further reviewed the expected scan times and workflow for contrast-enhanced imaging when both breasts are scanned in a screening environment. Discussions also covered the proposed protocol and management of lesions and tumors visible only on IzoView Breast CT and not on digital breast tomosynthesis, and how the reference standard or "truth" for these cases would be determined to support evaluation of radiologist performance.

Izotropic's FDA Consultant, Dr. Kyle Myers reflects on the discussion:

"*I thought the Izotropic- FDA pre-submission discussion was very positive. Given the large number of points for which Izotropic's approach to the clinical data collection and study design are in alignment with the FDA's expectations, we were able to focus on a small number of remaining questions from the Agency. Having Dr. Martin Yaffe and Dr. John Boone lay out their consistent finding that the estimated benefit of this technology, in terms of the additional cancers found, is around 10 times the relative risk due to the radiation to the patients was a great place to close out the meeting."*

For congruence and per the FDA's procedures, the Company will submit meeting minutes to the FDA for their review prior to additional disclosure.

About Izotropic:

More information about Izotropic Corporation can be found on its website at izocorp.com and by reviewing its profile on SEDAR at sedarplus.ca.

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