

## **NEWS RELEASE**

### IZOTROPIC MODIFIES MARKET APPROVAL PATHWAY & STRATEGY

**VANCOUVER, BC JUNE 20, 2023** – **Izotropic Corporation** ("**Izotropic**" or the "**Company**") (CSE: **IZO**) (OTCQB: **IZOZF**) (FSE: **1R3**), a medical device company commercializing IzoView, a 360-degree computed tomography (CT) imaging system designed for breast imaging and cancer diagnosis, announced that it is modifying its U.S. FDA market approval pathway and strategy by deferring its plan to undertake a Class III device classification requiring Pre-Market Approval (PMA) and will initially pursue regulatory clearance as a <u>Class II device</u>, such as a <u>510(k) pathway</u>.

The modified regulatory strategy is expected to offer the following benefits:

- Significantly shorten the FDA filing and approval timeline allowing for commercial launch and clinician access as early as 2H 2024, 2-3 years earlier than similar under the Class III strategy.
- Save the Company at least \$10+ million in pre-commercial investment by not requiring a large, expensive, multi-site diagnostic clinical study.
- Increase customer return on investment by providing clinicians with a broader intended use compared to a single indication.

Over the past three years, Izotropic has been pursuing a market authorization strategy to classify IzoView as a Class III medical device through a PMA submission to the U.S. FDA. The data required for a PMA submission would be acquired through a clinical study on a large number of patients at multiple sites across the U.S. In preparation for releasing milestone, timeline, and costing information to shareholders, and in order to secure the necessary capital to conduct the clinical study and PMA filing, an operational plan was completed in April of this year to finalize definitive and disclosable information to enable the Company to move forward. After the operational plan was completed, it revealed deep ramifications tied to the cost and the product's time to market. Specifically, it was estimated that costs to market were three times higher than initially predicted before factoring in operating costs, and the timeline was twice as long as initially anticipated at a conservative four years to market. Equipped with this new information, Izotropic's Board of Directors immediately decided to investigate, create, and implement an alternative pathway to commercialize IzoView.

The modified regulatory pathway allows for a near-term first FDA pre-market filing as a Class II device with an intended use of IzoView as a tool for non-invasive breast tissue characterization for use by licensed healthcare practitioners as an adjunct to mammography. This type of intended use statement, as a characterization tool (vs. a device that claims diagnostic performance), is analogous to most existing imaging systems, including CT products, provides for earlier utilization and adoption, and does not require any further product development modifications. A Class II filing involves standardized testing but does not require lengthy and expensive clinical studies.

Izotropic has taken the following actions in step with the modified market approval pathway and strategy:

- Engaged <u>Matrix Medical Devices</u> to represent Izotropic in regulatory approval filings and ongoing protocols and maintenance with the U.S. FDA.
- Realigned the Company's internal development team to pursue the modified strategy.
- Initiated pre-market filing submission documentation slated for completion in Q3 (calendar) of this year.

ON BEHALF OF THE BOARD Mr. Robert Thast, CEO Cell: 604-220-5031

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# **About Izotropic Corporation**

More information about Izotropic Corporation can be found on its website at izocorp.com and by reviewing its profile on SEDAR at <u>sedar.com</u>.

# **Forward-Looking Statements**

This document may contain statements that are "Forward-Looking Statements," which are based upon the current estimates, assumptions, projections, and expectations of the Company's management, business, and its knowledge of the relevant market and economic environment in which it operates. The Company has tried, where possible, to identify such information and statements by using words such as "anticipate," "believe," "envision," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate" and other similar expressions and derivations thereof in connection with any discussion of future events, trends or prospects or



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These statements are not guarantees of performance and involve risks, including those related to capital requirements and uncertainties that are difficult to control or predict, and as such, they may cause future results of the Company's activity to differ significantly from the content and implications of such statements. Forward-Looking Statements are pertinent only as of the date on which they are made, and the Company undertakes no obligation to update or revise any Forward-Looking Statements to reflect new information or the occurrence of future events or circumstances unless otherwise required to do so by law. Neither the Company nor its shareholders, officers, and consultants shall be liable for any action and the results of any action taken by any person based on the information contained herein, including, without limitation, the purchase or sale of Company securities. Nothing in this document should be deemed to be medical or other advice of any kind. All images are for illustrative purposes only. IzoView is not yet approved for sale.