January 15, 2025

Izotropic Announces Team Leading Clinical Study Design and FDA Regulatory Submissions

-New FDA Consultant is the former Director of the Division of Imaging, Diagnostics, and Software Reliability at the U.S Food and Drug Administration-

-New Biostatistical Consultant is the former Deputy Director of the Biostatistics and Data Management Center of the American College of Radiology Imaging Network, an NIH-funded cooperative that conducts clinical trials to evaluate the use of diagnostic imaging and image-guided treatments for cancer, has decades of successful experience in design and analysis of clinical studies of medical imaging devices supporting U.S. Food and Drug Administration approval applications -

-New Regulatory Consultant is the former VP of Regulatory Affairs, Clinical Affairs, and Quality Assurance for iCAD (NASDAQ: ICAD), a medical device manufacturer that offers computer-aided detection solutions for cancers including breast, and technology platforms including hardware and software for radiation therapy treatment-

VANCOUVER and SACRAMENTO, January 15, 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 Dr. Kyle J. Myers, Dr. Alicia Toledano, and Mr. John DeLucia are providing consulting services in key roles within the Company's regulatory division.

Supported by Izotropic's core team, Dr. Myers and Dr. Toledano have led the design and development of the regulatory strategy and clinical study design presented in the Company's recent pre-submission to the U.S. FDA to indicate the Company's first medical imaging device, IzoView- a dedicated breast CT imaging system, adjunctive to digital breast tomosynthesis (DBT or 3D mammography) for breast cancer screening in asymptomatic women with dense breast tissue.

As esteemed industry experts, Dr. Myers and Dr. Toledano have worked closely with Izotropic's management and advisors to determine a viable plan that expedites access to IzoView's breakthrough ultra-high-resolution technology for the 50% of the breast cancer screening patient

population in the U.S. who have dense breasts and that are presently underserved with the current standard-of-care imaging modalities.

Mr. John DeLucia, as a well-respected Regulatory Consultant, is representing Izotropic in its pre-submission interactions with FDA while ensuring the Company's proposals, documentation, filings, and communications are coherent with the organization’s complex compliance processes.

Dr. Myers is the former director of the Division of Imaging, Diagnostics, and Software Reliability at the U.S. Food and Drug Administration, where the FDA "develops methods for evaluating the image quality of emerging imaging systems; develops methods for characterizing new medical image display devices; evaluates the dose reduction potential of new image reconstruction methods, and… also develops state-of-the-art methods for the design of clinical trials involving imaging devices and the evaluation of resulting trial data to enable more efficient and effective utilization of imaging data and more powerful clinical studies[1].” In this role, she led “research programs in medical imaging systems and software tools including 3D breast imaging systems and CT devices, digital pathology systems, medical display devices, computer-aided diagnostics, biomarkers and assessment strategies for imaging and other high-dimensional data sets from medical devices[2]”. Dr. Myers earned a doctorate in optical sciences from the University of Arizona and belongs to the National Academy of Engineering. She is a fellow of the International Society for Optics and Photonics (SPIE), the American Institute for Medical and Biological Engineering (AIMBE), the American Association of Physicists in Medicine (AAPM), and Optica.

Dr. Toledano is the President of Biostatistics Consulting, LLC, which specializes in the design and analysis of clinical studies of medical imaging and in vitro diagnostic devices and works with companies in clinical stages of product development, from pilot studies to pivotal trials in support of FDA approval applications. She has specific expertise in study designs and statistical methods for evaluating diagnostic tests, particularly methods for correlated data, which arise from multi-reader, multi-case (MRMC) studies of medical imaging devices. While a faculty member at Brown University’s Center for Statistical Sciences, she served as deputy director of the American College of Radiology Imaging Network (ACRIN) Biostatistics and Data Management Center, the Protocol Statistician on seven ACRIN multicenter trials, and as a faculty statistician on the Digital Mammography in Screening Trial (DMIST); she is the recipient of two ACRIN Outstanding Contribution Awards. Dr. Toledano has served on FDA Medical Device Advisory Committees since 1998 and received an FDA Advisory Committee Service Award (In recognition of distinguished service) for service as a member of the Panel for Radiologic Devices. She earned master’s and doctoral degrees in Biostatistics from the Harvard School of Public Health.

Mr. DeLucia brings over 30 years of experience in the industry, where he has held senior positions in the areas of Regulatory and Clinical Affairs and Quality Assurance with iCAD, C.R Bard, Smiths Medical, ACMI, Genzyme, Pfizer Hospital Products, and various start-ups. He is the former VP of Regulatory Affairs, Clinical Affairs, and Quality Assurance for various companies including iCAD, a U.S.-based medical device manufacturer that offers computer-aided detection solutions for cancers including breast, and technology platforms including hardware and software for radiation therapy treatment, a role in which he held for over a decade, and has further breast cancer-related experience having managed a large clinical trial for a novel tomosynthesis breast cancer detection system.

In addition to Dr. Myers, Dr. Toledano, and Mr. DeLucia, the submission team comprised of Izotropic core team members and advisors including Medical Physicist, Technology Founder, and Company Director Dr. John Boone; Chief Operating Officer and IzoView Lead Engineer Dr. Younes Achkire; Biomedical Engineer and Izotropic's Head of Imaging Technology Dr. Andrew Hernandez; and Mathematician, Medical Physicist, Professional Researcher, and Izotropic Advisor Dr. Craig Abbey.

Dr. Myers and Dr. Toledano will continue to support the Company's regulatory efforts long-term through the completion of its forthcoming clinical study for FDA approval of IzoView adjunct to DBT.

Sources:

[1] (2019, September 6). *Division of Imaging, Diagnostics, and Software Reliability*. U.S. Food & Drug Administration. Retrieved January 11, 2025, from https://www.fda.gov/about-fda/cdrh-offices/division-imaging-diagnostics-and-software-reliability

[2] (n.d.). *Dr. Kyle J. Myers*. SPIE. Retrieved January 11, 2025, from https://spie.org/profile/Kyle.Myers-7697

About Izotropic:

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

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 future operating or financial performance, although not all forward-looking statements contain these identifying words.

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 has not yet been approved or cleared for sale.

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