



ABK Biomedical announces FDA 510(k) clearance of Easi-Vue™ embolic microspheres for the embolization of arteriovenous malformations and hypervascular tumors

HALIFAX, Nova Scotia, Sept 12, 2022 – [ABK Biomedical, Inc.](#), an innovative medical device company dedicated to the research, development, and commercialization of advanced imageable embolic therapies, announces FDA 510(k) clearance of Easi-Vue embolic microspheres for the treatment of patients suffering from arteriovenous malformations and hypervascular tumors.

Arteriovenous malformations (AVMs) occur when capillaries, veins, and arteries don't develop properly and may lead to cutaneous discoloration, sensitivity, pain, and vascular bleeding. Vascular embolization, performed by interventional radiologists, is an effective therapy for addressing the symptoms of patients suffering from this condition.

Hypervascular tumors occur in both benign and malignant states and are characterized by blood supply from an abnormally large number of blood vessels. Microspheres embolization reduces or eliminates the blood flow to these tumors and is an effective interventional radiology therapy for treating this disease state.

Aravind Arepally, MD, FSIR, and Chief Medical Officer of ABK Biomedical said "The evolution of embolic therapies to treat these complex disease states has been notable in recent years. Now, with Easi-Vue embolic microspheres, interventional radiologists have a highly calibrated, see-and-do technology capable of visually targeted placement using conventional x-ray and fluoroscopy systems. This microspheres technology and proprietary controlled-concentration delivery system have the potential to improve patient outcomes."

"We are excited to achieve FDA 510(k) clearance for this new technology that has the potential to advance the field of embolic therapies", said Gary Donofrio, Chief Business Officer of ABK Biomedical. "This represents a major milestone for ABK as our team continues to execute our product development objectives. We will partner with key physicians to understand the range of clinical utilization and optimization of Easi-Vue therapy. Additionally, ABK continues to significantly advance the development program of our Eye90 microspheres® radio-embolic technology that's being investigated for the treatment of patients with unresectable Hepatic Cellular Carcinoma (HCC). Easi-Vue embolic microspheres share core technologies and design characteristics with Eye90 microspheres. Both devices continue to add to our knowledge base regarding the clinical experience of the first glass radiopaque embolic microspheres therapy."

About ABK Biomedical Inc.

ABK Biomedical is a clinical-stage development company focused on researching, developing, and commercializing medical device therapies to improve treatment outcomes and the lives of patients with benign and malignant hypervascular tumors. ABK Biomedical holds intellectual property in the areas of inorganic polymer microspheres and unique administration systems. The company possesses advanced intellectual capital and its own R&D and manufacturing

facilities for developing and commercializing unique embolotherapy products. Eye90 microspheres are considered investigational products and are NOT approved for use in any regulatory jurisdiction outside of approved clinical trials.

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