



ABK Biomedical Announces FDA IDE Approval for a Multi-Center Pivotal Study of Eye90 microspheres® in Hepatocellular Carcinoma

HALIFAX, Nova Scotia, May 30, 2023 – [ABK Biomedical, Inc.](#), an innovative, medical device company dedicated to the research, development, and commercialization of advanced imageable embolic medical devices, has received approval for its Investigational Device Exemption (IDE) application from the U.S. Food and Drug Administration (FDA) to commence a multi-center pivotal clinical study in the United States for its Eye90 microspheres yttrium-90 (Y90) radioembolization therapy.

The pivotal clinical study, Route90, is designed to evaluate the safety and efficacy of Eye90 microspheres in patients living with unresectable Hepatocellular Carcinoma (HCC). The Route90 study will evaluate HCC tumors' response rates and duration of response from Eye90 microspheres treatment as co-primary endpoints. Eye90 microspheres is the first and only imageable Y90 microspheres device. The study also includes endpoints to evaluate safety, the potential benefits of intra-procedural visualization, and the ability to perform post-treatment CT-dosimetry with imageable microspheres.

Andrew Kennedy, MD, FACRO, Physician in Chief of Radiation Oncology at Sarah Cannon Cancer Institute will serve as Principal Investigator for the Route90 study. Dr. Kennedy is one of the early pioneers of Y90 radioembolization research and treatment. "I'm excited to participate and lead the Route90 study. Eye90 microspheres is a significant and meaningful technology advancement to Y90 radioembolization therapy not seen in over almost two decades since the current therapies became clinically available," said Dr. Kennedy.

"We're motivated to begin this pivotal study and assess the Eye90 microspheres technology in a large well-controlled, well-designed study. We continue to build upon the results of our first-in-man Eye90 microspheres study conducted recently in New Zealand. The initial results from this study are highly encouraging with an excellent safety profile and robust tumor response rates", said Aravind Arepally, MD, FSIR, ABK Biomedical's Chief Medical Officer.

[Mike Mangano, President, and CEO, ABK Biomedical](#), said: "FDA approval of this pivotal study is a significant milestone for ABK. The ABK team has worked tirelessly to develop this unique technology. We have created extensive manufacturing and supply-chain efficiencies, established robust quality assurance in all our processes, and collaboratively engaged regulatory bodies for proper guidance. We believe this will become a seminal study for treating patients with unresectable HCC. We designed our Y90 radioembolization technology to align with the most recent, advanced Y90 treatment methods, techniques, and appropriate patient populations. This has the promise to significantly improve outcomes for targeted patients living with unresectable HCC".

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 is considered an investigational product and is not approved for use in any regulatory jurisdiction outside of approved clinical trials.

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