ABK Biomedical Announces First Patient Treated in its Multi-Center Pivotal Study of Eye90 microspheres® in Hepatocellular Carcinoma

HALIFAX, Nova Scotia, Oct 24, 2023 – ABK Biomedical, Inc., an innovative, medical device company dedicated to the research, development, and commercialization of advanced imageable embolic medical devices, today announced the first patient treated in its Route90 US IDE Pivotal study. The Eye90 microspheres radioembolization procedure was performed by Eric A. Wang, MD, FSIR, with Charlotte Radiology in Charlotte NC.

“This is an exciting time for multidisciplinary, liver cancer treatment teams.” said Dr. Wang. “Hepatocellular Cancer (HCC) is a severe form of cancer. Over the past 40 years, liver cancer incidence rates have more than tripled, and death rates have more than doubled during that time period³. Eye90 radioembolization represents an advancement in liver-directed HCC therapy. Eye90 microspheres with multi-modality imaging, controlled visible administration, and personalized dosimetry is advancing the field of radioembolization. We’re excited to be a part of this pivotal study and look forward to establishing the effectiveness and safety of this new Y90 radioembolization technology.”

The Route90 pivotal clinical study is designed to evaluate the safety and efficacy of Eye90 microspheres in patients living with unresectable HCC. The 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 in-procedure 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.

“While Y90 radioembolization is established as a safe and effective therapy for the treatment of HCC, rigorous prospective clinical studies are needed to establish credible data to support FDA PMA approval.”, said David Dobrowski, VP of Clinical and Regulatory Affairs, ABK Biomedical. “The Route90 study will collect the high-quality data long needed with Y90 radioembolization therapy establishing a new standard of treatment. We’re enthusiastic to treat our first patient and continue to work diligently with the top US Y90 treatment centers and all our highly motivated investigators on enrolling patients to complete the study”.

Andrew Kennedy, MD, FACRO, Physician in Chief of Radiation Oncology at Sarah Cannon Cancer Institute is Principal Investigator for the Route90 study and one of the early pioneers of Y90 radioembolization research and treatment. “The Route90 pivotal study will not only confirm the effectiveness of Eye90 treatment but will also establish the importance of 3D radiation dosimetry in advancing therapy and patient outcomes. This is a significant milestone for all those involved at ABK, the clinical research team at Charlotte Radiology, and the multiple other sites that are about to begin patient enrollment. We look forward to rigorously and efficiently completing this important trial to offer the HCC community a long-overdue, advanced Y90 radioembolization therapy”, said Dr. Kennedy.

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.

Contact

ABK Biomedical, Gary Donofrio, 617-513-9575, g.donofrio@abkbiomedical.com