ABK Biomedical announces that its Eye90 microspheres® device has been granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA)

HALIFAX, Nova Scotia, December 5, 2023 – ABK Biomedical, Inc., an innovative, medical device company dedicated to the research, development, and commercialization of advanced imageable embolic therapies, announces its Eye90 microspheres device has been granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA). This designation is for the proposed Eye90 microspheres indication for the treatment of patients living with unresectable Hepatocellular Carcinoma(HCC). Breakthrough designation is granted to devices that may provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions for which no approved alternative exists.

"We are pleased with the FDA's decision to grant Breakthrough Device Designation for Eye90 microspheres Y90 radioembolization device. This confirms our belief that Eye90 represents an important evolution of radioembolization technology with the potential to significantly improve patient outcomes. Our discussions with the FDA have been productive, and this designation will allow us to streamline interactions with FDA and bring this product to market in an efficient manner. We look forward to executing our Route90 trial and our continued collaboration with the FDA", said Mike Mangano, President, and CEO of ABK Biomedical.

ABK Biomedical recently initiated enrollment in Route90, an FDA IDE approved pivotal, prospective, multicenter trial to establish the safety and efficacy of Eye90 microspheres in patients with unresectable HCC.

Dr. Aravind Arepally, Chief Medical Officer of ABK Biomedical, stated, "Eye90 microspheres radioembolization marks a significant breakthrough in the treatment of HCC. This medical device allows us to leverage multi-modality imaging, facilitate controlled visual administration and offers personalized dosimetry. This gives us the opportunity to further advance the field of Y90 radioembolization. We're excited that FDA also recognizes the potential of ABK's technology to improve patient outcomes."

About FDA Breakthrough Devices Program

The FDA Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products which are subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request (De Novo request). This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for PMA approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

About ABK Biomedical, Inc.

ABK Biomedical is a 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.

Contacts

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