

# HCC Pivotal Study



## General Information

**Therapy:** Y90 Radioembolization

**Device:** Eye90 microspheres®

### Principal Investigator:

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**Study Phase:** Pivotal Phase III

**Sites:** 20

**Subjects:** 120 enrolled / treated

**Follow up:** 12 months

**Enrollment Starts:** August 2023

### Unique Device Features:

- Radiopaque glass Y90 microspheres
- Visible on x-ray-based imaging
- Personalized unit dose patient prescription
- Advanced controlled administration device

### Therapy Features:

- Partition based treatment planning model
- Post procedure dosimetry

## Study Title

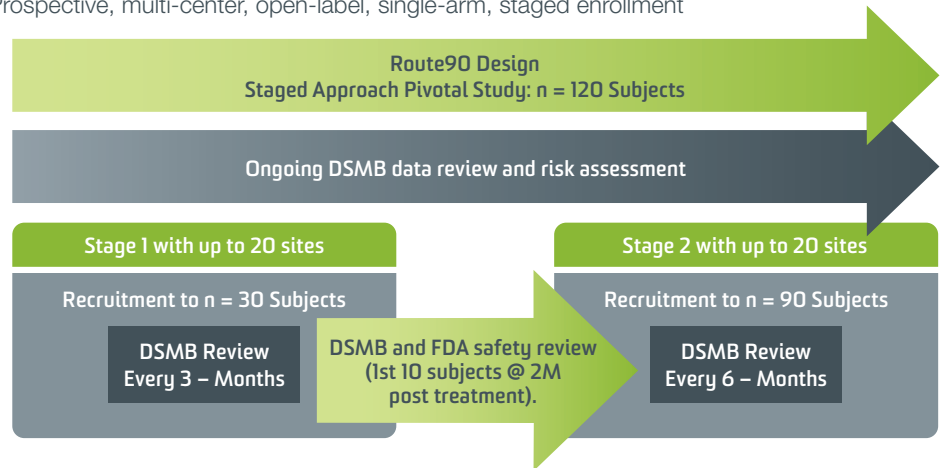
Radioembolization Oncology trial Utilizing Transarterial Eye90 (ROUTE 90) for the treatment of Hepatocellular Carcinoma (HCC)

## Indication

Eye90 microspheres® is intended for use as internal radiation brachytherapy for local tumor control in patients with unresectable Hepatocellular Carcinoma (HCC).

## Design

Prospective, multi-center, open-label, single-arm, staged enrollment



## Eligible Patients

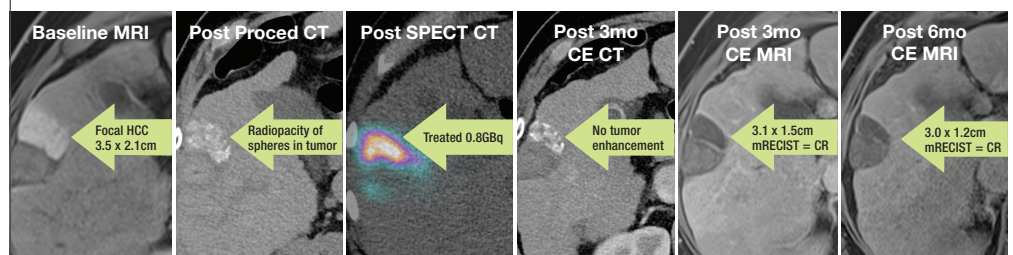
- Confirmed diagnosis of HCC, LIRADS 5 or biopsy
- One lesion  $\geq 2$  cm in diameter, no more than 3 lesions
- Max 3 lesions and single lesion size  $\leq 8$  cm & sum tumor dimensions of  $\leq 12$  cm
- Evidence that  $> 33\%$  of the total liver volume is disease-free
- No extra hepatic disease
- Child Pugh Class A, ECOG 0-1, BCLC A, B, C

## Endpoints

**Effectiveness:** Confirmed ORR and Duration of Response  $> 6$  months using local mRECIST

**Safety:** Incidence of Adverse Events and Serious Adverse Events

**Example:** Patient imaging potential with Eye90 microspheres®



Eye90 microspheres® is considered an investigational product and is NOT FDA-approved for use.

Manufactured by: ABK Biomedical Inc.  
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