



TheraSphere™ Y-90 Glass Microspheres | LEGACY STUDY

A robust study confirming TheraSphere as a neoadjuvant or standalone therapy in treating HCC.

Salem R, Johnson GE, Kim E, Riaz A, Bishay V, Boucher E, Fowers K, Lewandowski R, Padia SA. Yttrium-90 Radioembolization for the Treatment of Solitary, Unresectable Hepatocellular Carcinoma: The LEGACY Study. Hepatology. 2021 Mar 19. doi: 10.1002/hep.31819.

STUDY OBJECTIVE

To assess local tumor control and duration of response following treatment with Y-90 glass microspheres in patients with unresectable solitary HCC lesions.

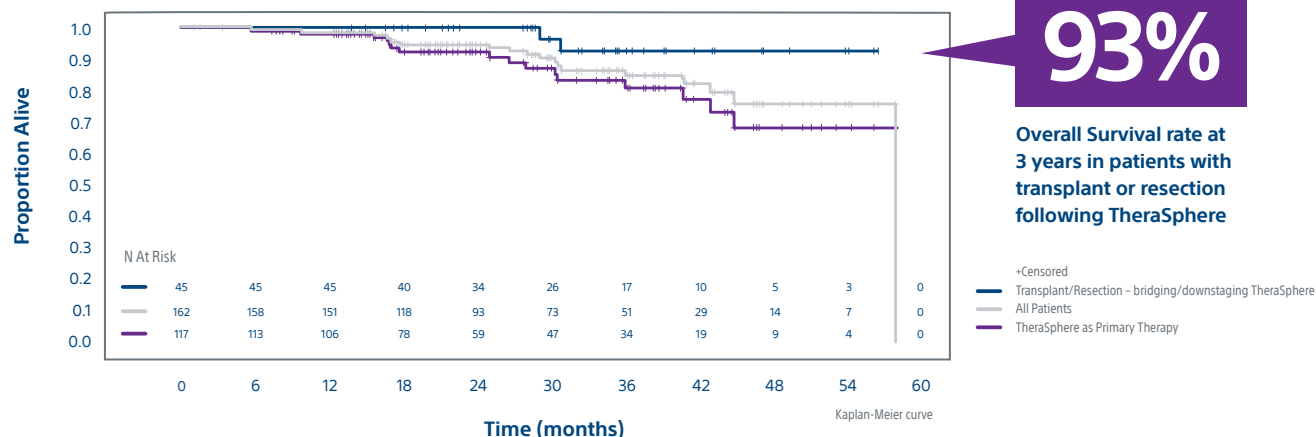
KEY RESULTS

100%

Patients in the LEGACY study responded to TheraSphere treatment(s)

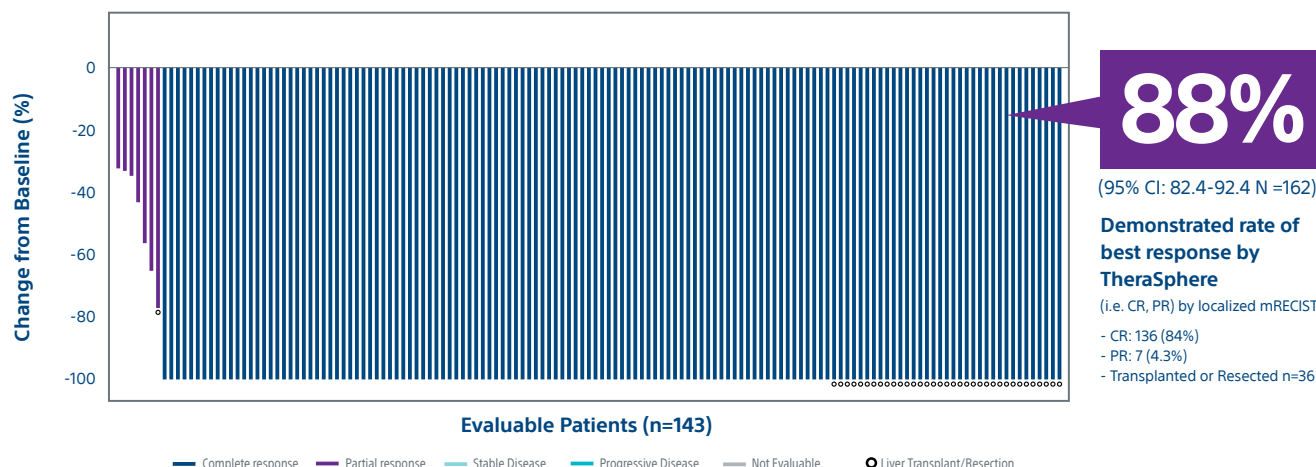
- 96.8% with one TheraSphere treatment
- 100% with two TheraSphere treatments

Overall Survival (Treated Population)



Tumor Response

(Best Response in evaluable population, localized mRECIST)



THERASPHERE™ Y-90 Glass Microspheres | LEGACY STUDY

STUDY DESIGN

Multi-center, single-arm, retrospective study conducted at 3 U.S. sites.* Consecutive patients meeting the eligibility criteria were treated with TheraSphere Y-90 glass microspheres at each site between January 2014 and December 2017.

FIRST AND ONLY

- Used highly clinically relevant criteria for localized tumor control (mRECIST)
- Reported a median dose to perfused liver volume of 410 Gy
- Demonstrated 100% of patients achieved CR or PR (localized mRECIST)

KEY ELIGIBILITY CRITERIA

Unresectable solitary lesions (≤ 8 cm); Selective, lobar, or mixed administration of Y-90 glass microspheres (TheraSphere); Treatment purpose (neoadjuvant to transplantation or resection or stand-alone treatment); Child-Pugh score A; BCLC A or BCLC C (ECOG 1); No prior liver transplantation, resection, locoregional treatment or systemic therapy; No portal vein thrombosis or extrahepatic disease.

KEY BASELINE CHARACTERISTICS (N=162)

	% of patients		
Median Age: 66 years	≥ 75 years: 17.9	BCLC A: 60.5	BCLC C: 39.5
Median Tumor Size: 2.6 cm (0.9-8.1 cm)			

PRIMARY STUDY ENDPOINTS WERE MET

determined by Blinded Independent Central Review (BICR)

Objective Response Rate

72.2%¹
(n=117/162)

Objective Response Rate (ORR) defined as CR or PR using localized mRECIST (defined as the response within the Y-90 glass microsphere treatment area) with confirmation of response (> 4 weeks).

Duration of Response

76.1%²
(n=89/117)
(≥ 6 months)

Duration of Response³ (DoR) using localized mRECIST

Safety: Majority of adverse events were mild and resolved without medical intervention

LEGACY STUDY CONCLUSION

LEGACY is the first multicenter study to report a high median perfused volume absorbed dose of 410 Gy with TheraSphere, which resulted in an 88% best response, excellent and durable tumor control and high overall survival rate in patients with early and advanced HCC.

HCC: hepatocellular carcinoma; BCLC: Barcelona Clinic Liver Cancer staging system; Y-90: Yttrium-90; Gy: Gray; IQR: Interquartile Range

*University of Washington, Seattle, WA; Northwestern University, Chicago, IL; Mount Sinai Health System, New York, NY

1. Complete Response (CR) and Partial Response (PR) within the treatment area according to localized mRECIST

2. Duration of Response (DoR) According to localized mRECIST

3. Median follow-up was 29.9 months [95% CI: 24.7, 34.6]

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**TheraSphere™ Y-90 Glass Microspheres
Indications, Safety, and Warnings**

<https://www.bostonscientific.com/therasphere-indications>

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