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THERASPHERE™ Y-90 Glass Microspheres | TARGET STUDY

A global real-world retrospective study that confirms TheraSphere for HCC as safe and effective, demonstrating predictable clinical outcomes across a broad patient population in 8 countries.

Lam, M., Garin, E., Maccauro, M. et al. A global evaluation of advanced dosimetry in transarterial radioembolization of hepatocellular carcinoma with Yttrium-90: the TARGET study. Eur J Nucl Med Mol Imaging (2022). https://doi.org/10.1007/s00259-022-05774-0

STUDY OBJECTIVE

Establish the relationships between:

- Normal tissue adsorbed dose (NTAD) and occurrence of grade 3 or higher hyperbilirubinemia
- Tumor absorbed dose (TAD) and Objective Response Rate (ORR)
- TAD and Overall Survival (OS)

STUDY DESIGN

Key Patient Characteristics

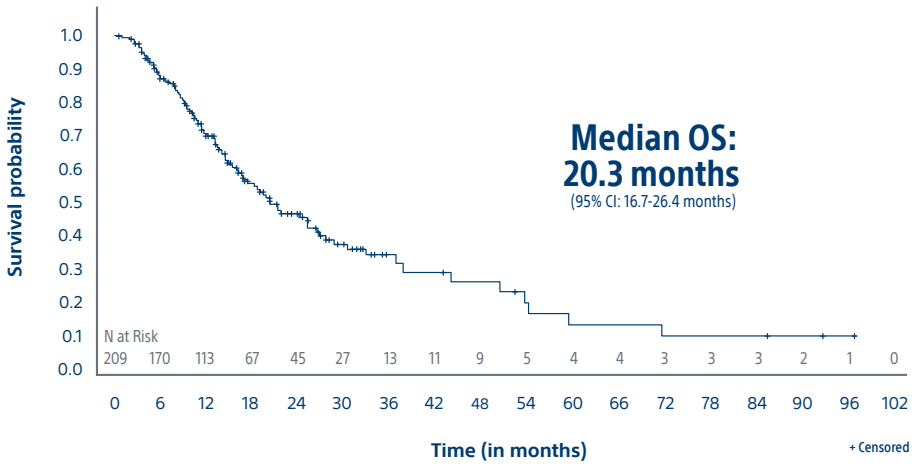
- Mainly Intermediate and Advanced HCC: 32.5% BCLC B and 54.5% BCLC C
- 7 cm median target lesion
- 33% PVT*

Dosimetry Approach

- Investigator review of patient chart and dosimetry calculation
- Retrospective dosimetry evaluation with multi-compartment approach using Simplicit^{90}Y™ personalized dosimetry software to determine TAD and NTAD

*TheraSphere not indicated for patients with PVT.

RESULTS



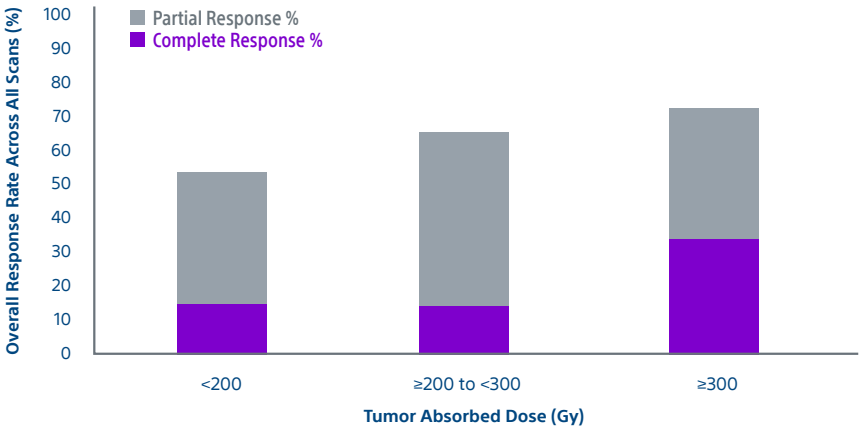
70.8% ORR*
for the target lesion (mRECIST)

61.7% ORR**
for all lesions (mRECIST)

20.3 months
median Overall Survival

*95% CI = 64.3 - 76.6%
**95% CI = 55.0 - 68.0%

TUMOR ABSORBED DOSE WAS PREDICTIVE OF RESPONSE[1,2]



Responders had a

17% higher

mean tumor absorbed dose (225.5 Gy*) compared with non-responders (188.3 Gy**)

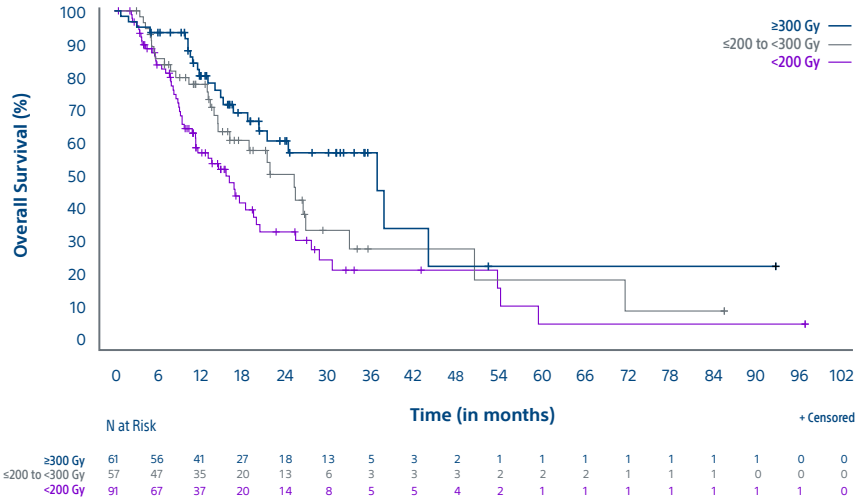
*95% CI = 201.0 - 253.0 Gy
**95% CI = 164.6 - 215.3 Gy; p=0.046

1. Total perfused tumor absorbed dose and best response (61.7%) according to mRECIST
2. Non-responders (defined as stable disease, progressive disease, or non-evaluable) are not represented in the graph

TUMOR ABSORBED DOSE WAS PREDICTIVE OF OVERALL SURVIVAL

KAPLAN-MEIER OVERALL SURVIVAL CURVES

Total Perfused Tumor Aborbed Dose by Subgroups



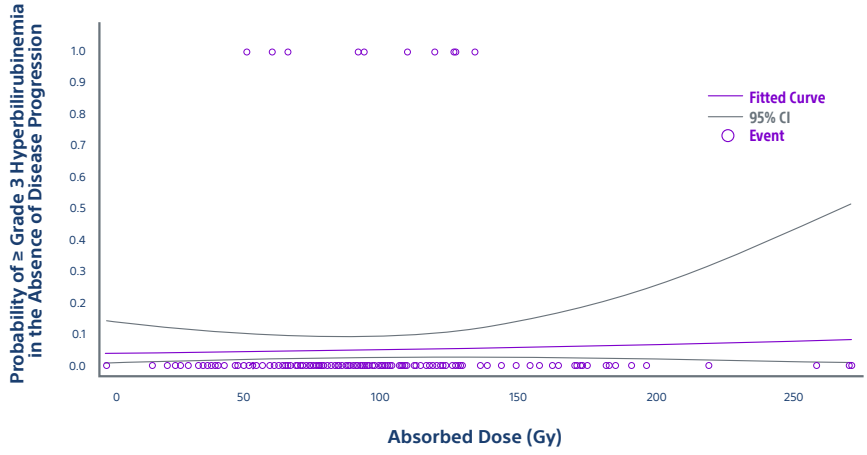
Median Overall Survival

>300 Gy - 36.7 months
(95% CI: 20.2 - 43.9 months)

>200 - <300 Gy - 25.1 months
(95% CI: 14.5 - 32.9 months)

<200 Gy - 16.1 months
(95% CI: 11.3 - 19.4 months)

LOW RATE OF ≥ GRADE 3 HYPERBILIRUBINEMIA CONFIRMS SAFETY OF TARGET STUDY



Only 4.8% of patients (10/209) experienced ≥ Grade 3 hyperbilirubinemia in the absence of disease progression

Regarding the low rate of event, no correlation could be established with normal tissue absorbed dose (p=0.6 for NTAD)

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PATIENT CHARACTERISTICS	TREATED POPULATION
Parameter	**(N=209) N (%)**
Median age (range), years	66.0 (27-87)
Gender, male	166 (79.4%)
ECOG Status	
0	135 (64.6%)
1	67 (32.1%)
≥2	7 (3.4%)
BCLC Status	
A	27 (12.9%)
B	68 (32.5%)
C	114 (54.5%)
Child-Pugh Status	
A (5-6)	187 (89.5%)
B 7	22 (10.5%)
Unilobar or Bilobar Disease	
Unilobar	148 (70.8%)
Bilobar	61 (29.2%)

PATIENT CHARACTERISTICS	TREATED POPULATION
Parameter	**(N=209) N (%)**
With PVT	69 (33.0%)
Location of Target Lesion	
Left Lobe	30 (14.4%)
Right Lobe	179 (85.6%)
Target Lesion Longest Diameter (RECIST 1.1)	
≥3 to <5 cm	41 (19.6%)
≥5 to <8 cm	72 (34.4%)
≥8 cm	96 (45.9%)
Total Number of Lesions (target and non-target)	
1	145 (69.4%)
2	45 (21.5%)
3	14 (6.7%)
4-10	5 (2.4%)

The TARGET study provides real-world data confirming a significant association between TAD and objective response and between TAD and OS in HCC patients treated with Y-90 glass microspheres.

STUDY TAKEAWAYS

Dose Matters

Deliver the highest dose to the tumor that is safely possible to maximize patient response and improve survival

Predictability

Predictable results across 8 countries using multi-compartmental dosimetry using Simplicit^{90}Y personalized dosimetry software

Consistency

Like the LEGACY study and DOSISPHERE-01 trial results, the TARGET study reinforces the association between higher tumor absorbed dose and clinical outcomes

ThereSphere™ Y-90 Glass Microspheres Indications, Safety, and Warnings

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

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