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THERASPHERE™ Y-90 Glass Microspheres

DOSISPHERE-01 Trial Summary

Level 1 evidence of 26.7 month overall survival for HCC patients treated with TheraSphere using personalized dosimetry compared to 10.7 months with standard single compartment dosimetry.

STUDY OBJECTIVE:

Multi-center, prospective, randomized, investigator-sponsored phase II trial designed to compare the clinical outcomes of SIRT with TheraSphere in patients with advanced HCC using two pre-treatment dosimetry determination methods: (1) Standard, single-compartment dosimetry (SDA); defined as a uniform distribution of absorbed dose within the perfused volume – both tumor and normal liver or (2) Personalized dosimetry (PDA); defined as multi-compartment Y-90 distribution of absorbed dose within the perfused volume that accounts for preferential blood flow into the tumor compared with normal parenchyma.

PRIMARY ENDPOINT:

Response rate of the index lesion at Month 3 according to EASL criteria using a mITT population* by investigator assessment.

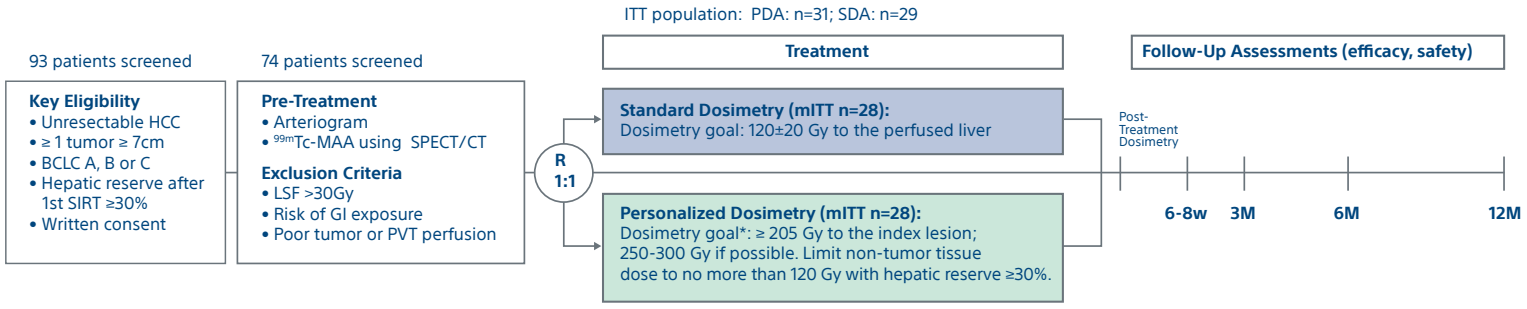
*mITT: randomized and treated patients

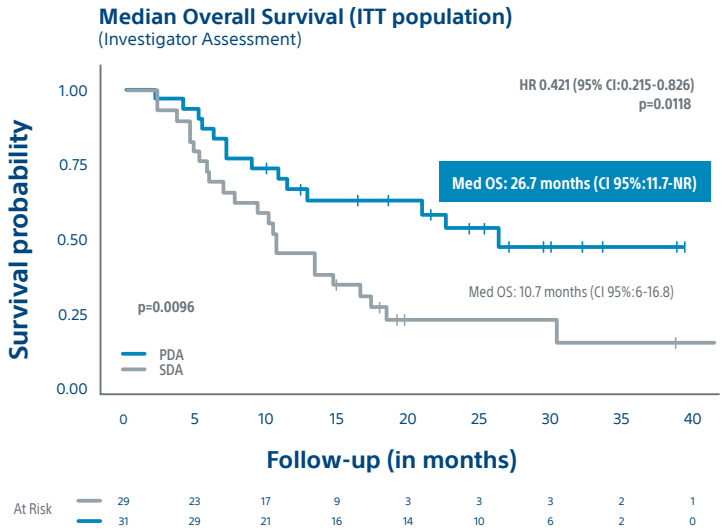
MAIN SECONDARY ENDPOINTS:

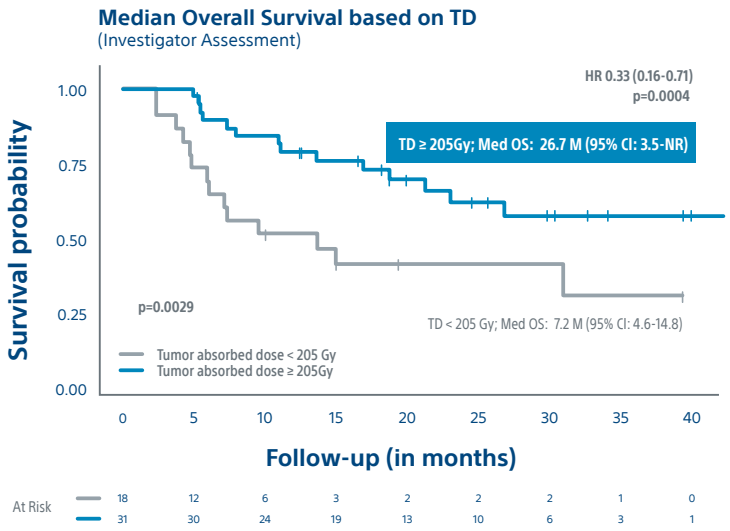
Overall Survival | PFS | Dose-response relationship | Safety

STUDY DESIGN:

Multi-centre, randomized (1:1), prospective, phase II study







DOSISPHERE-01 Trial Summary | 12 month results

PATIENT DEMOGRAPHICS (mITT population)

Parameter	PDA (n=28)	SDA (n=28)
Age (median±SD)	64.8±10.1	62.5±13.1
Male (%)	92.9	92.9
Underlying cirrhosis (%)	85.7	85.7
Child-Pugh Status (%)	CP A5: 78.6 CP A6: 21.4 CP B7: 0	CP A5: 78.6 CP A6: 21.4 CP B7: 0
Mean Total Bilirubin (µM/L±SD)	14.63±6.43	13.63±5.78
ECOG (%)	0: 57.1 1: 42.9	0: 46.4 1: 53.6
PVT present (%)	67.9	75.0
Index lesion (mean, cm)	10.36±2.44	10.67±2.79
Tumoral involvement (mean±SD)	23.01±13.95	23.97±14.2

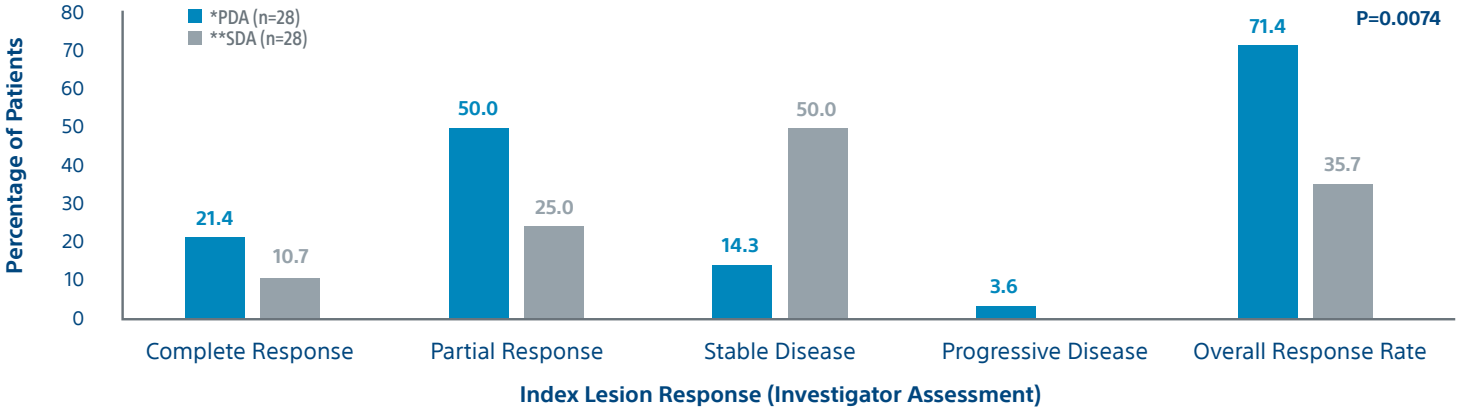
*No significant difference in baseline characteristics between groups

TREATMENT CHARACTERISTICS AND DOSIMETRY (mITT population)

Investigator Assessments	PDA arm (n=28)	SDA arm (n=28)	P value
Number of Y-90 glass microspheres treatment	One treatment, n=26 Two treatments, n=2	One treatment, n=24 Two treatments, n=4	ns
Activity administered GBq (mean, min-max)	3.98 (1.3-9.6)	2.72 (1.0-5.1)	ns
AD to perfused liver (Gy) Mean (±SD)	178.4±59.9	124.5±27.3	0.0001
% of patients with AD to perfused liver> 150 Gy	67.9	7.1	<0.0001
AD to index lesion (Gy) Mean (±SD)	342.6±131.5	221.3±139.4	0.0033
% of patients with AD to index lesion > 205 Gy	92.8	32.1	0.0008
AD to perfused normal tissue (Gy) Mean (±SD)	94.7±30.3	64.5±36.6	0.0038

*AD=absorbed dose

PRIMARY END POINT: INDEX LESION RESPONSE RATE AT 3 MONTHS USING EASL IN THE mITT POPULATION



*reasons for censoring: received another anti-cancer treatment before M3 evaluation (n=2), no evaluation at M3 evaluation (n=1) (10.7%)
**reasons for censoring: Early deaths (before M3) (n=2), no evaluation at M3 (n=1), start another anti-cancer treatment before M3 evaluation (n=1) (14.3%)

LIVER ADVERSE EVENTS (Grade ≥3) Related to Y90*

	PDA (n=35)	SDA (N=21)
Patients with ≥ 1 AE	3 (8.6%)	3 (14.3%)
Death	1 (2.9%)	1 (4.8%)
Liver AEs	4 (11.4%)	5 (23.8%)
Ascites	1 (2.9%)	1 (4.8%)
Encephalopathy	0	0
GI hemorrhage	0	2 (4.8%)
Bilirubin increase/jaundice	1 (2.9%)	2 (9.5%)
Hepatic failure	2 (5.7%)	0

*patients allocated to either PDA or SDA based on treatment received (dose received) versus allocation by randomization

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Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

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