



TheraSphere™ Y-90 Glass Microspheres | PROACTIF STUDY

PROACTIF: A Prospective, Real-World, Y-90 Study with TheraSphere for the Treatment of Liver Malignancies: Interim Analysis of 873 Hepatocellular Carcinoma (HCC) Patients

HIGH OVERALL SURVIVAL IN INTERMEDIATE AND ADVANCED HCC PATIENTS IN PROACTIF, THE LARGEST, PROSPECTIVE, REAL-WORLD Y-90 STUDY OF PRIMARY LIVER CANCER IN 1,000+ PATIENTS*

PROACTIF Overview

STUDY OBJECTIVE AND ENDPOINTS

The study aims to gather data on effectiveness, patient quality of life (QoL), and safety with use of TheraSphere Y-90 glass microspheres in real-world clinical settings in France.

Primary Endpoints

Overall survival (OS) from time of TheraSphere treatment and QoL, as assessed using the functional assessment of Cancer Therapy – Hepatobiliary (FACT-Hep) questionnaire.

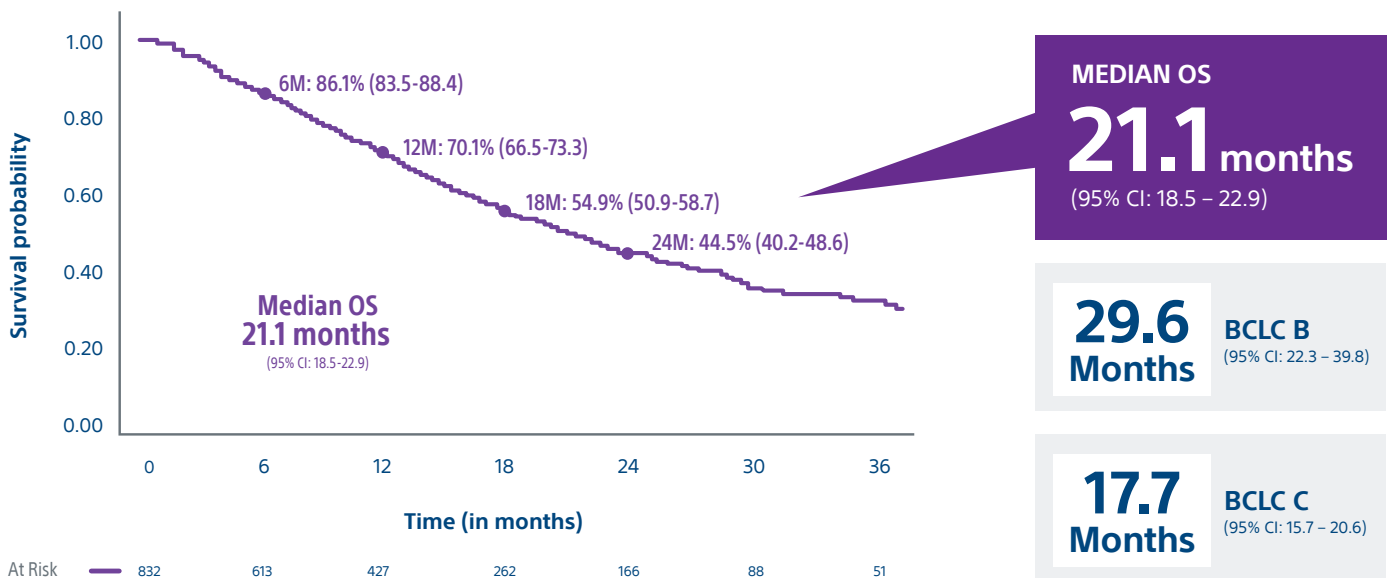
Key Secondary Endpoints

Grade ≥ 3 AEs, SAEs, tumor response, tumor marker response, subsequent therapy, and dosimetry evaluations.

First real-world, multi-center Y-90 study of primary liver cancer that builds on previously published TheraSphere landmark trials.

INTERIM HCC ANALYSIS - 873 PATIENTS ACROSS 32 SITES*

HIGH OVERALL SURVIVAL FOR INTERMEDIATE & ADVANCED STAGE HCC PATIENTS



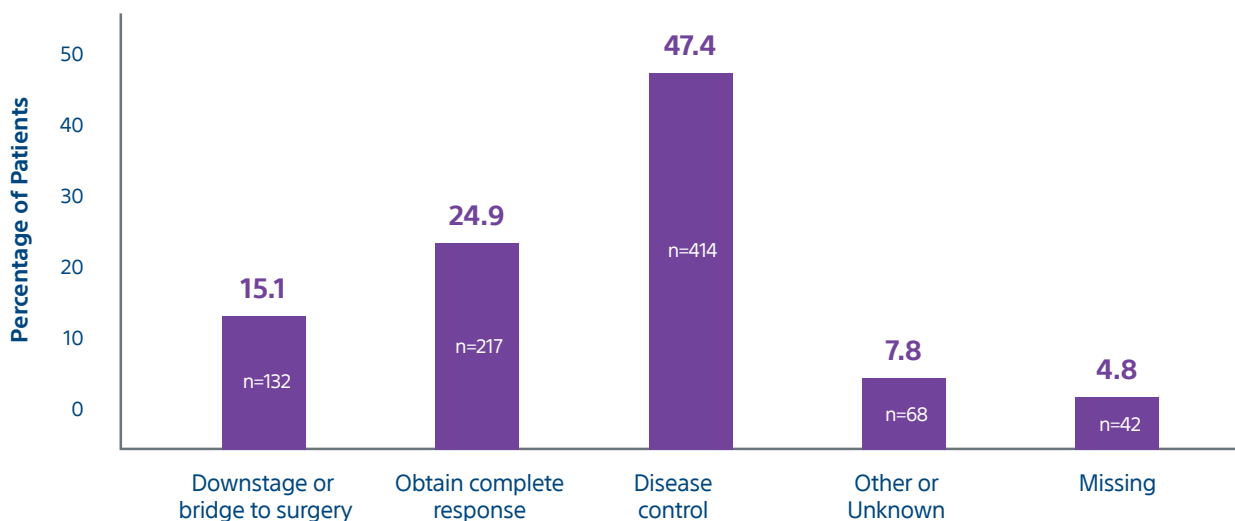
SUBGROUP ANALYSIS DEMONSTRATED PROLONGED SURVIVAL IN PATIENTS WHO RECEIVED SELECTIVE TREATMENT, WERE ALBI GRADE 1, OR HAD UNILOBAR DISEASE*

Subgroup	n	Median OS	95% CI
Administration			
Selective	424	23.1 M	20.8-27.4
Non-selective	371	17.8 M	15.5-21.7
ALBI Grade			
1	327	29.4 M	24.8-36.3
2 or 3	377	17.0 M	14.8-20.6
Disease extent			
Unilobar	650	21.7 M	19.7-24.8
Bilobar	157	16.0 M	13.7-18.3

DATA FROM 30+ SITES USED CONTEMPORARY TECHNIQUES AND DOSING*



REAL-WORLD TREATMENT SCENARIOS SPAN CURATIVE TO PALLIATIVE INTENT



MAJORITY OF PATIENTS WERE INTERMEDIATE / ADVANCED STAGE WITH INDEX LESIONS > 5CM*

PATIENT DEMOGRAPHICS & DISEASE CHARACTERISTICS

Variable	n(%)	Variable	n(%)	Variable	n(%)
Age, median (years)	71	ECOG performance status		BCLC stage	
≥ 18 to < 65	228 (26.1)	0	494 (56.6)	O/A	1 (0.1)/ 28 (3.2)
≥ 65 to < 75	339 (38.8)	1	278 (31.8)	B	299 (34.2)
≥ 75	264 (30.2)	2	12 (1.4)	C	491 (56.2)
Missing	42 (4.8)	≥3	4 (0.5)	D	1 (0.1)
Gender		Missing	85 (9.7)	Missing	53 (6.1)
Male	781 (89.5)	Extrahepatic disease		Portal vein thrombosis	
Female	92 (10.5)	Yes	35 (4.0)	Yes	337 (38.6)
Etiology (top 5)		No	788 (90.3)	% segmental/lobar/main	19.4/15.6/3.4
Alcohol	421 (48.2)	Not assessed/Missing	50 (5.7)	No	521 (59.7)
Metabolic	203 (23.3)	ALBI grade		Missing	15 (1.7)
Hepatitis B/C	58 (6.6)/157 (18.0)	1	327 (37.5)	Total lesions	
None	145 (16.6)	2-3	377 (43.2)	1	356 (40.8)
Unknown/Other	93 (10.7)	Missing	169 (19.4)	2-4	400 (45.8)
Comorbidities (top 5)		Child-Pugh		>5	94 (10.8)
Alcohol intake sequelae	482 (55.2)	A	688 (78.8)	Missing	23 (2.6)
Arterial Hypertension	463 (53.0)	B	57 (6.5)	Index lesion diameter	
Diabetes	379 (43.4)	C	1 (0.1)	Median size, cm	6.20 cm
Smoking	333 (38.1)	Missing	127 (14.5)	≤ 5 cm	299 (37.9)
Coronary Artery Disease	110 (12.6)			> 5 cm	490 (62.1)

CONCLUSION

Interim analysis of 873 HCC patients across 32 sites demonstrated high overall survival in intermediate and advanced HCC patients. Data builds on evidence from previously published landmark trials such as DOSISPHERE and TARGET.

	PROACTIF (n=873)	DOSISPHERE-01 (ITT) ¹		TARGET ² (n=209)
		MCD (n=31)	SCD (n=29)	
Study Design	Prospective, Real-World Study	Prospective, Randomized Controlled Trial		Retrospective, Real-World Study
BCLC A/B/C/D (%)	3.2/34.2/56.2/0.1	0/13/87/0	0/10/90/0	12.9/32.5/54.5/NAP
ECOG 0/1/≥2 (%)	56.6/31.8/1.8	58/24/0	0/48/52	64.6/32.1/3.4
CP A/B	78.8/6.5	A5: 81 A6 or B7: 19	A5: 79 A6 or B7: 21	89.5/10.5
PVT: none (%) seg/lobar/main (%)	59.7 19.4/15.6/3.4	36 33/30 (lobar or main)	27 31/41 (lobar or main)	66 NAV
Unilobar/bilobar disease (%)	74.5/18	58/42	41/59	70.8/29.2
Median OS (months)(95% CI)	21.1 (18.5-22.9)	26.6 (11.7-NR) 5 yr follow-up^{**}: 24.8 (11.0-36.5)³	10.7 (6.0-16.8) 5 yr follow-up^{**}: 10.7 (6.0-14.9)³	20.3 (16.7-26.4)

Data in above table as of December 2023.

This study is sponsored by Boston Scientific. Final results are expected in 2025 and will include full patient population with additional information on quality of life, safety and dosimetry.

1. Garin E, Tselikas L, Guiu B et al. Personalized versus standard dosimetry approach of selective internal radiation therapy in patients with locally advanced hepatocellular carcinoma (DOSISPHERE-01): a randomised, multicentre, open-label phase 2 trial. *Lancet Gastroenterol Hepatol*. 2021; 6: 17-29.

2. 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>.

3. Garin E, Tselikas L, Guiu B et al. Long-Term Overall Survival After Selective Internal Radiation Therapy for Locally Advanced Hepatocellular Carcinomas: Updated Analysis of DOSISPHERE-01 Trial. *J Nucl Med*. 2024;65(2):264-269. Published 2024 Feb 1. doi:10.2967/jnumed.123.266211

Garin E, Bailly C, Letang A et al. Abstract No. 257 - Featured Abstract The PROACTIF French Registry Study of Y-90 Glass Microspheres for the Treatment of Liver Malignancies: Interim Analysis of 670 Hepatocellular Carcinoma (HCC) Patients. *J Vasc Interv Radiol*. 2024 Mar 25(3):S113 doi: <https://doi.org/10.1016/j.jvir.2023.12.295> (updated dataset for oral presentation at SIR March 2024)

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