



PROACTIF: A prospective, real-world Y-90 study with TheraSphere for the treatment of liver malignancies: Interim data of 168 intrahepatic cholangiocarcinoma (ICC) patients.

## THERASPHERE DEMONSTRATED OVERALL SURVIVAL OF 18.1 MONTHS FOR 168 ICC PATIENTS IN PROACTIF

#### **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.

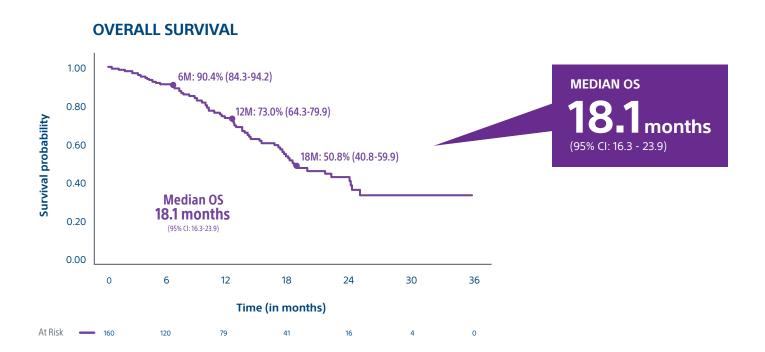
## **Key Secondary Endpoints**

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

PROACTIF is the largest, prospective, real-world Y-90 study of primary liver cancer in 1,000+ patients.

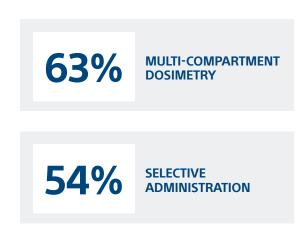
Therasphere Microspheres are indicated in the treatment of all hepatic malignancies.

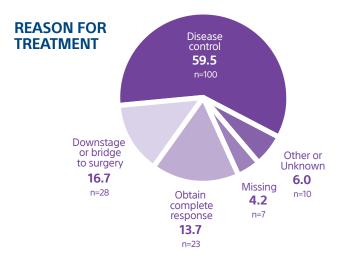
# INTERIM DATA OF 168 ICC PATIENTS ACROSS 32 SITES



# **THERASPHERE**™ Y-90 Glass Microspheres | PROACTIF STUDY

### DATA FROM 32 SITES USED CONTEMPORARY TECHNIQUES AND DOSING





## MAJORITY OF PATIENTS HAD SINGLE LESION WITH INDEX LESION > 5CM

### PATIENT DEMOGRAPHICS & DISEASE CHARACTERISTICS

Variable	n(%)	Variable	n(%)	Variable	n(%)
Age, median (years)	69	Liver Disease Etiology		Portal Vein Thrombosis	
≥ 18 to < 65	51 (30.4)	No underlying disease	109 (64.9)	Yes	28 (16.7)
≥ 65 to < 75	57 (33.9)	Alcohol	30 (17.9)	Cruoric*	2 (7.1)
≥ 75	51 (30.4)	Hepatitis B/C	11 (5.4)	Tumoral	26 (92.9)
Missing	9 (5.4)	Metabolic	19 (11.3)	ECOG Permormance status	
Gender		Unknown/Other	17 (10.1)	0-1	146 (86.9)
Female	88 (52.4)	Total Lesions		2-3	5 (3.0)
Comorbidities (top 5)		1	84 (50.0)	Missing	17 (10.1)
None	47 (28.0)	2-4	54 (32.1)	ALBI Grade	
Alcohol	45 (26.8)	>5	25 (14.8)	1	86 (51.2)
Arterial Hypertension	68 (40.5)	Missing	5 (3.0)	2 or 3	39 (23.2)
Hyperglycemia (diabetes)	41 (21.4)	Index Lesion Diameter		Missing	43 (25.6)
Tobacco	44 (26.2)	Mean size, mm 70.7		Child Pugh	
Liver Disease		>5 cm	99 (67.8)	A	77 (45.8)
Normal/No History	92 (54.8)	Extrahepatic Disease		В	7 (4.2)
Cirrhosis	36 (21.4)	Yes	7 (4.2)	Missing	84 (50.0)
Fibrosis	17 (10.1)	No	158 (94.0)		
Missing	23 (13.7)	Missing	3 (1.8)		

\*Non-malignant thrombus

## CONCLUSION

Appropriately selected ICC patients treated with TheraSphere demonstrated an overall survival of 18.1 months using Y-90. This dataset helps build foundational real-world data for an under-studied disease state.

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.

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