ASX/MEDIA RELEASE **5th June 2017**

SIR*ve*NIB Study Data Presented at ASCO Annual Meeting

Sydney, Australia; 5th June 2017 – Sirtex Medical Limited (ASX:SRX) announces the oral abstract of the SIR*ve*NIB clinical study comparing SIR-Spheres® Y-90 resin microspheres versus sorafenib (Nexavar®, Bayer Healthcare Pharmaceuticals) in patients with non-resectable advanced hepatocellular carcinoma (HCC) was presented at the gastrointestinal (non-colorectal) cancer session at the American Society of Clinical Oncology (ASCO) Annual Meeting today[1]. The 360 patient SIR*ve*NIB study was conducted in predominately Asian patients, across 11 Asian countries and New Zealand, with 27 centres participating.

Dr David N. Cade, Chief Medical Officer of Sirtex Medical said "We congratulate the SIR*ve*NIB study investigators on their oral abstract presentation at ASCO. The SIR*ve*NIB study data verifies the important role of SIR-Spheres as an alternative treatment to sorafenib for advanced HCC in an Asian population, given the significant safety and toxicity benefits conferred, with no significant difference in median overall survival outcomes."

Professor Pierce Chow, Principal Investigator of the SIR*ve*NIB study and Senior Consultant Surgeon at the National Cancer Centre Singapore and the Singapore General Hospital said "We found that the Asian patients with locally advanced HCC who were treated with Y-90 resin microspheres had a significantly better tumour response rate of 16.5% compared to 1.7% for sorafenib ($p<0.001$) in the intent to treat, or ITT analysis, and 23.1% for SIRT compared to 1.9% ($p<0.001$) in the treated population, which represents the patients who actually received their allocated treatment. They also experienced almost a two-fold decrease in severe adverse events (grade ≥3; 27.7% *vs*. 50.6%; $p<0.0001$) compared with those treated with sorafenib."

"The comparative data on side effects reported in the SIR*ve*NIB study unequivocally favoured Y-90 resin microspheres over sorafenib," Prof. Chow said. "In addition to two-fold fewer severe AEs, we observed about one fourth as many adverse events (60.0% *vs.* 84.6% $p<0.0001$) as well as fewer serious AEs [SAEs] (20.8% *vs.* 35.2%; $p=0.009$). Specifically, patients treated with Y-90 resin microspheres reported substantially less fatigue (3.8% *vs.* 15.4%), diarrhoea (1.5% *vs*. 29.6%), hand-foot skin reaction (0.8% *vs.* 54.9%), alopecia (0% *vs.* 9.9%) as well as hypertension (0% *vs.* 14.8%) than those treated with sorafenib."

Professor Bruno Sangro, Director of the Liver Unit at Clinica Universitaria de Navarra, Professor of Medicine at the University of Navarra School of Medicine, and senior researcher in the National Biomedical Research Network Center for Liver and Digestive Diseases commented "The SIR*ve*NIB study results confirm those from the SARAH study, in terms of the good safety profile of SIRT using Y-90 resin microspheres, which was significantly better tolerated than sorafenib. We now have two large, prospective, randomised controlled trials that show that SIRT using Y-90 resin microspheres in HCC patients with cirrhosis, is a safe procedure. Since liver toxicity could have been a potential issue, the safety profile of SIRT with Y-90 resin microspheres is very reassuring. Although this is a negative primary endpoint, as SIR*ve*NIB was designed to show superiority in overall survival, it shows that for centres that treat HCC, it is worth having SIRT as an alternative to sorafenib so that the multidisciplinary tumour boards can consider the most appropriate treatment option for their patients."

The SIR*ve*NIB study is the largest ever randomised controlled trial in a predominately Asian population to provide Level 1 evidence comparing a liver-directed therapy, namely SIR-Spheres Y-90 resin microspheres, against the standard of care chemotherapy agent sorafenib.

Head Office
Level 33, 101 Miller Street
North Sydney, NSW 2060
Australia

Americas
300 Unicorn Park Drive
Woburn, MA 01801
United States

Europe, Middle East & Africa
Josef-Schumpeter-Allee 33
53227 Bonn
Germany

Asia Pacific
50 Science Park Road, #01-01
The Kendall Science Park II
Singapore 117406

A copy of Professor Chow's presentation is attached.

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About SIR*ve*NIB

SIR*ve*NIB is a Phase III Multi-Centre Open-Label Randomised Controlled Trial of Selective Internal Radiation Therapy (SIRT) using SIR-Spheres Y-90 resin microspheres Versus Sorafenib (Nexavar®, Bayer HealthCare Pharmaceuticals, Germany) in Locally Advanced Hepatocellular Carcinoma. The primary objective of this study is to assess the efficacy of SIRT as compared with sorafenib in patients with locally advanced liver cancer in terms of overall survival (OS). ClinicalTrials.gov Identifier: NCT01135056. www.sirvenib.com.

About Hepatocellular Carcinoma (HCC)

Hepatocellular Carcinoma (HCC) is the most common form of primary liver cancer – cancer that starts in the liver. It is the sixth most common cancer in the world and the second most common cause of cancer-related death[2].

About SIR-Spheres® Y-90 Resin Microspheres

SIR-Spheres Y-90 resin microspheres are a medical device used in interventional oncology and delivered via Selective Internal Radiation Therapy (SIRT), also known as radioembolisation, directly to liver tumours. SIR-Spheres Y-90 resin microspheres are approved for supply in key markets, such as the United States, European Union and Australia.

About Sirtex Medical

Sirtex Medical Limited (ASX:SRX) is an Australian-based global healthcare business working to improve outcomes in people with cancer. Our current lead product is a targeted radiation therapy for liver cancer. Over 73,000 doses have been supplied to treat patients with liver cancer at 1,060 medical centres in over 40 countries. For more information please visit www.sirtex.com.

For further information, please contact:

Investor Enquiries:

Dr David Cade
CMO
Sirtex Medical Limited
Phone: +61 (0) 2 9964 8400

Investor/Media Enquiries:

Dr Tom Duthy
Global Investor Relations Manager
Sirtex Medical Limited
Phone: +61 (0) 2 9964 8427
Email: tduthy@sirtex.com

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[1] Chow PKH *et al.* Phase III multi-centre open-label randomized controlled trial of selective internal radiation therapy (SIRT) versus sorafenib in locally advanced hepatocellular carcinoma: The SIRveNIB study. *2017 ASCO Annual Meeting; J Clin Oncol* 2017; **35** (Suppl): Abs 4002.

[2] GLOBOCAN 2012. Estimated cancer mortality, incidence and prevalence worldwide. http://globocan.iarc.fr/Default.aspx

Sirtex Medical Limited

SIR*ve*NIB Clinical Study

ASCO Oral Abstract Presentation

5 June 2017

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Phase III multi-centre open-label randomized controlled trial of selective internal radiation therapy (SIRT) versus sorafenib in locally advanced hepatocellular carcinoma: The SIRveNIB study.

Pierce K.H. Chow
National Cancer Center Singapore, Singapore
DukeNUS Medical School, Singapore

Mihir Gandhi
Singapore Clinical Research Institute, Singapore
DukeNUS Medical School, Singapore

THE Asia-Pacific Hepatocellular Carcinoma Trials Group

National Cancer Centre Singapore
SingHealth

DukeNUS Medical School

On behalf of

The Asia-Pacific Hepatocellular Carcinoma Trials Group
(http://www.scri.edu.sg/crn/asia-pacific-hepatocellular-carcinoma-ahcc-trials-group/about-ahcc/)
ClinicalTrials.gov: NCT01135056

SIRTeX

Disclosure

Pierce K.H Chow

- Advisory Role:
  - Sirtex Medical, Ltd
  - Ipsen
  - BMS
  - Oncosil
- Research Support:
  - Sirtex Medical, Ltd
  - National Medical Research Council, Singapore
  - Ipsen
  - Quintiles-IMS Health

Background

The majority of patients with Hepatocellular Carcinoma (HCC) have **locally advanced disease** (+/- PVT) at diagnosis.

Both SIRT and sorafenib have demonstrated efficacy in this group of patients but have different mechanisms of actions.

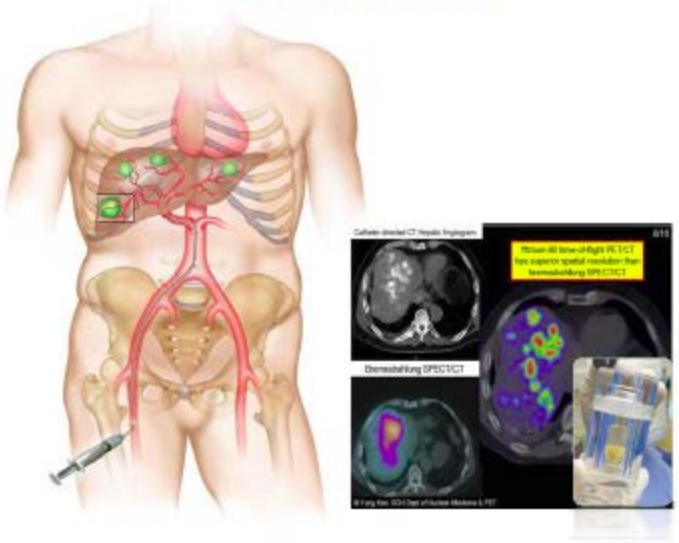
A definitive RCT comparing these 2 promising therapies in locally advanced HCC will impact on outcomes in a large number of patients and potentially change clinical practice.

[1] Llovet JM *et al. N Engl J Med.* 2008; 359: 378-90. [2] Llovett JM *et al. Lancet* 2002; 359: 1734–9. [3] Lo CM *et al. Hepatology* 2002; 35: 1164–71. [4] Llovett JM *et al. Hepatology* 2003; 37: 429–42. [5] Oliveri RS *et al. Cochrane Database Syst Rev* 2011;(3):CD004787. [6] Sangro B *et al. Hepatology* 2011; 54: 868–78. [7] Salem R *et al. Gastroenterology* 2010; 138: 52–64. Khor *et al. Hepatology International* 2014; 8:395-404

Different Therapeutic Classes

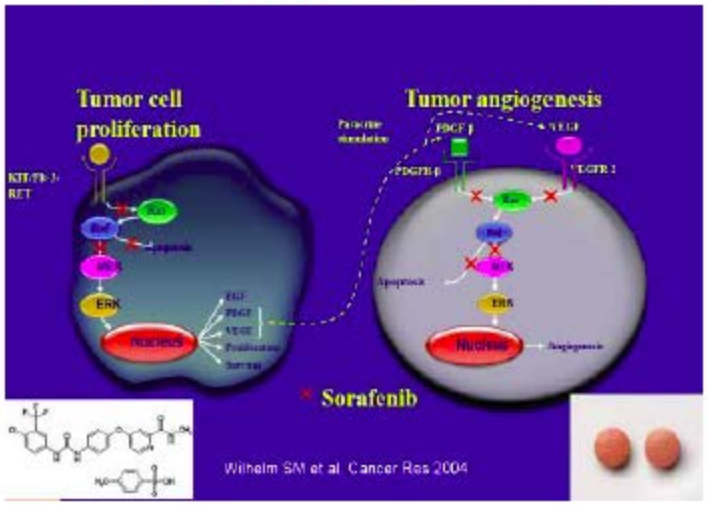
SIRT:

Brachytherapy



Sorafenib:

Oral molecular targeted therapy



Objectives

Primary objective

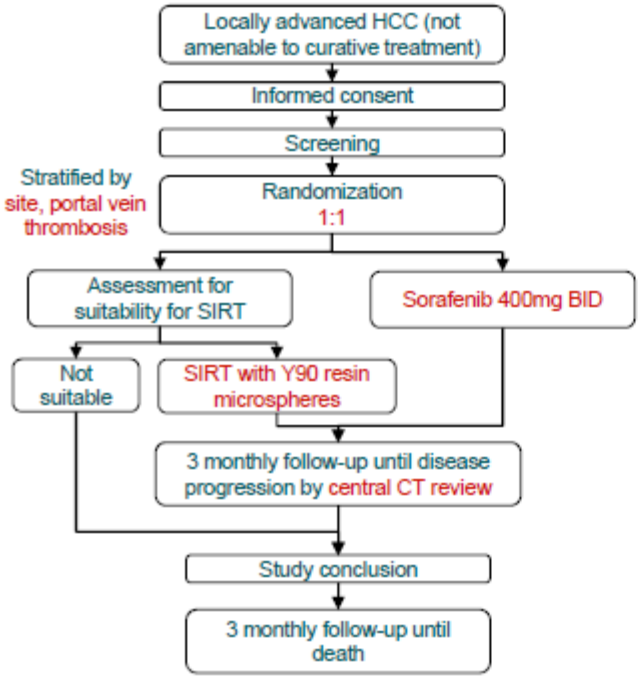
To assess the efficacy of SIRT with Y90 resin microspheres compared with sorafenib in patients with locally advanced liver cancer not amenable to curative therapies, with respect to overall survival (OS).

Secondary objectives

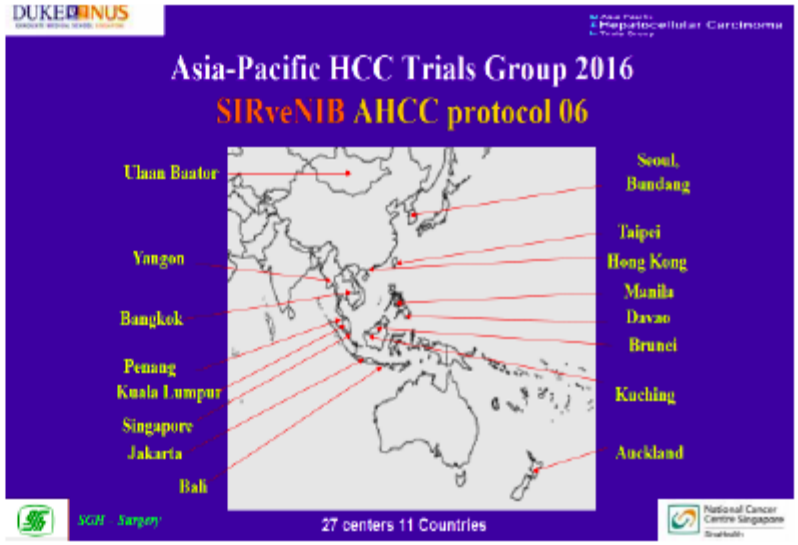
To compare SIRT with sorafenib for:

- Tumour response rate (RECIST 1.1)
- Disease control rate
- Time to disease progression (overall and in liver)
- Progression free survival (overall and in liver)
- Toxicity and safety (CTCAE 4.02)

Study Design and Assessments



An investigator-initiated open-label, phase III multi-center, RCT in locally advanced HCC with or without portal vein thrombosis (PVT)



Eligibility Criteria

- Unequivocal diagnosis of HCC (AASLD Criteria or histology) that is locally advanced but without extra-hepatic metastases
  - With or without portal vein thrombosis
  - BCLC B and BCLC C without distant metastases
- At least one lesion with dimension ≥ 10 mm
- Age 18 years and above
- ECOG performance status 0 – 1
- Child-Pugh A-B (up to 7 points)
- Adequate hematological, renal and hepatic function
- Life expectancy of at least 3 months
- Not having > 2 prior administrations of hepatic artery directed therapy
- No prior hepatic artery directed therapy within past 4 weeks

Sample size

- **Assumptions**

Median OS for SIRT = 14 months [Sangro *et al. Hepatology*. 2011;54(3):868–78]

Median OS for sorafenib = 9.35 months [Kang *et al. Ann Oncol*. 2008;19(Supplement 8):177]

Hazard ratio = 0.67

Type I error (two-sided) = 5%

Power = 90%

Built-in drop-out rate = 20%

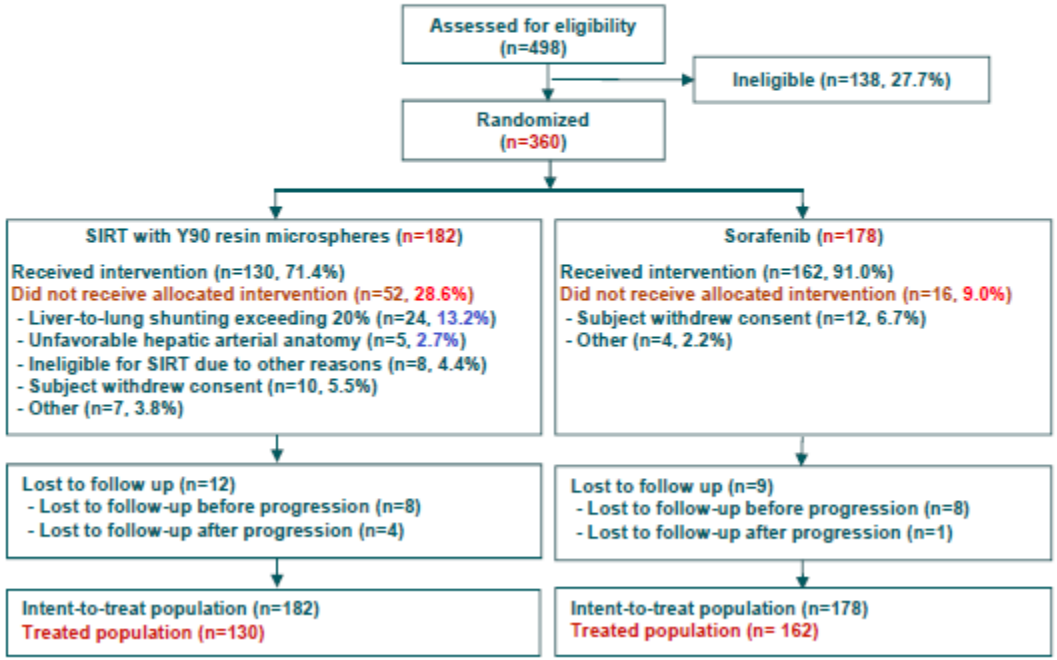
Accrual period = 3 years

Follow-up period = 2 years

- **Sample size (Using the Log-rank test)**

180 + 180 = 360 subjects (Final analysis at 266 deaths)

CONSORT Diagram



11 Asia-Pacific countries (27 sites)

Country	n (%)
Singapore	78 (21.7)
Myanmar	74 (20.6)
Philippines	57 (15.8)
Mongolia	39 (10.8)
Thailand	32 (8.9)
Indonesia	22 (6.1)
Malaysia	19 (5.3)
South Korea	17 (4.7)
Taiwan	13 (3.6)
New Zealand	8 (2.2)
Brunei	1 (0.3)

Baseline Characteristics

Characteristics	Intent-to-treat population			Treated population		
	SIRT (N = 182)	Sorafenib (N = 178)	P	SIRT (N = 130)	Sorafenib (N = 162)	P
Age (years), Mean (SD)	59.5 (12.9)	57.7 (10.6)	0.154	60.9 (11.5)	57.5 (10.6)	0.009
Male, n (%)	147 (80.8)	151 (84.8)	0.331	107 (82.3)	138 (85.2)	0.525
Body mass index (kg/m^2), Mean (SD)	23.2 (4.2)	24.0 (4.6)	0.089	23.2 (4.3)	24.1 (4.7)	0.089
Portal vein thrombosis, n (%)	56 (30.8)	54 (30.3)	1.000	30 (23.1)	48 (29.6)	0.232
ECOG status, n (%)			0.265			0.559
0	135 (74.2)	141 (79.2)		106 (81.5)	127 (78.4)	
1	47 (25.8)	37 (20.8)		24 (18.5)	35 (21.6)	
Child-Pugh stage, n (%)			0.613			0.455
A	163 (89.6)	156 (87.6)		117 (90.0)	142 (87.7)	
B	18 (9.9)	21 (11.8)		12 (9.2)	20 (12.3)	
BCLC stage, n (%)			0.239			0.427
A	0	1 (0.6)		0	1 (0.6)	
B	100 (54.9)	109 (61.2)		83 (63.8)	95 (58.6)	
C	81 (44.5)	68 (38.2)		46 (35.4)	66 (40.7)	
Tumor size >50% of liver, n (%)	43 (23.6)	43 (24.2)	1.000	23 (17.7)	35 (21.6)	0.462
Hepatitis, n (%)			0.484			0.653
B	93 (51.1)	104 (58.4)		68 (52.3)	94 (58.0)	
C	26 (14.3)	19 (10.7)		20 (15.4)	19 (11.7)	
B and C	4 (2.2)	5 (2.8)		3 (2.3)	2 (1.2)	

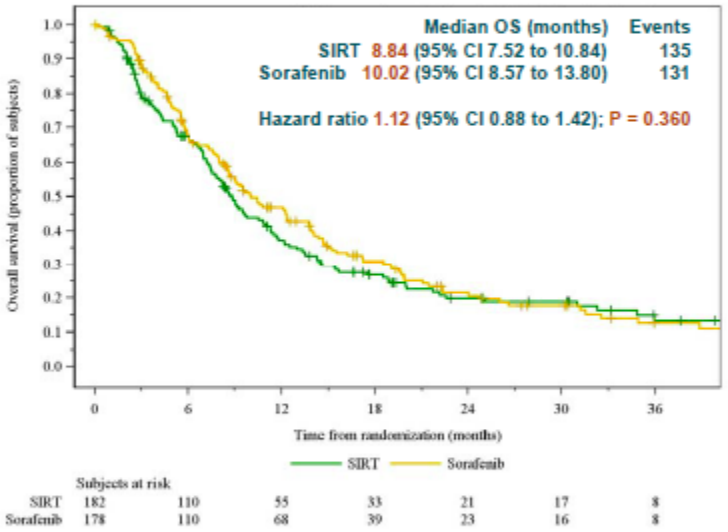
Study Treatments Exposure

- **SIRT (n = 130)**
  - Median time from randomization to treatment: 21.0 days
  - n=52 (28.6%) did not receive allocated SIRT
  - All subjects received single dose
  - Mean activity administered: 1.8 GBq
- **Sorafenib (n = 162)**
  - Median time from randomization to treatment start: 3.0 days
  - n=16 (9%) did not receive allocated sorafenib
  - Mean daily dose per subject: 644.5 mg
  - Median treatment duration: 13.8 weeks
  - Subjects with ≥ 80% adherence to planned doses: 88.9%

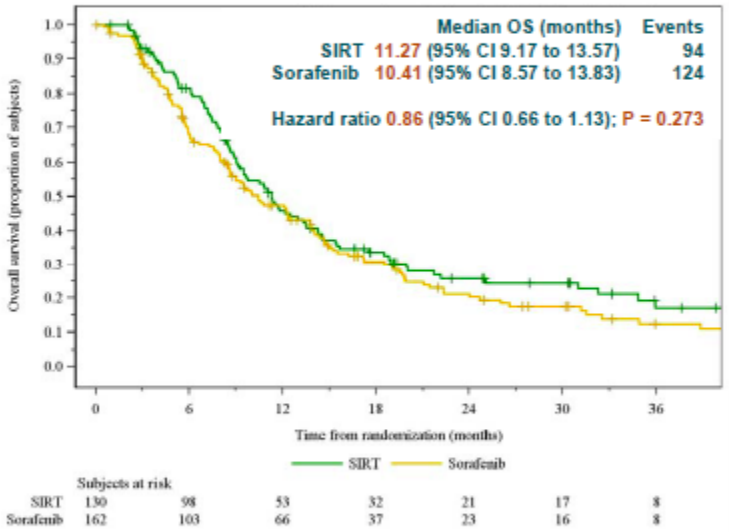
SIRT Treatment Centers

Efficacy: Overall Survival

- Intent-to-treat population



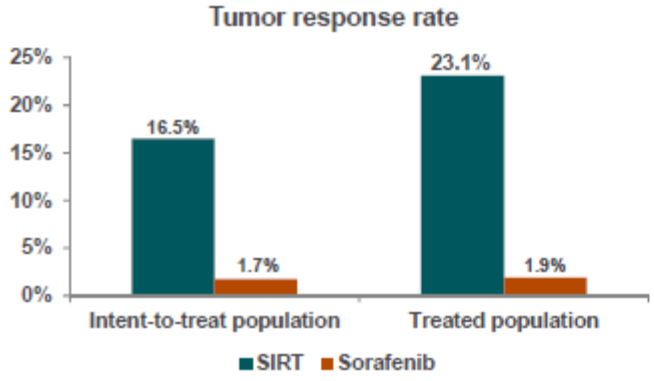
- Treated population

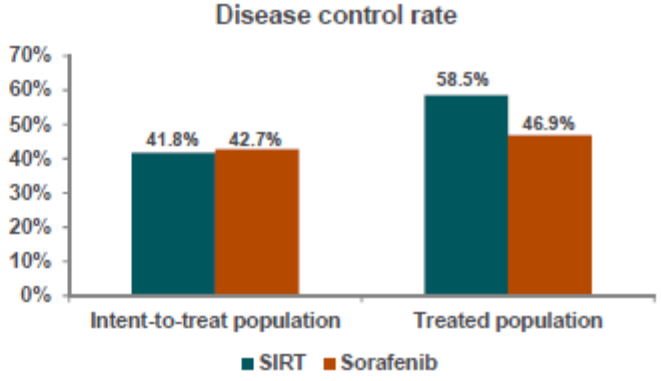


Efficacy: Tumor Response Rate and Disease Control Rate

	Intent-to-treat population			Treated population		
	SIRT (N = 182)	Sorafenib (N = 178)	P-value	SIRT (N = 130)	Sorafenib (N = 162)	P-value
Tumor response rate (CR + PR), n (%)	30 (16.5)	3 (1.7)	<.001	30 (23.1)	3 (1.9)	<.001
Disease control rate (CR + PR + SD), n (%)	76 (41.8)	76 (42.7)	0.915	76 (58.5)	76 (46.9)	0.059

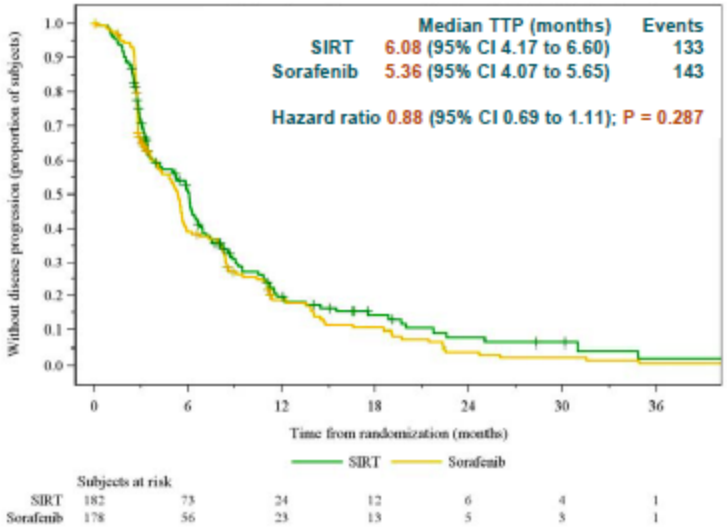
CR: Complete response; PR: Partial response; SD: Stable disease



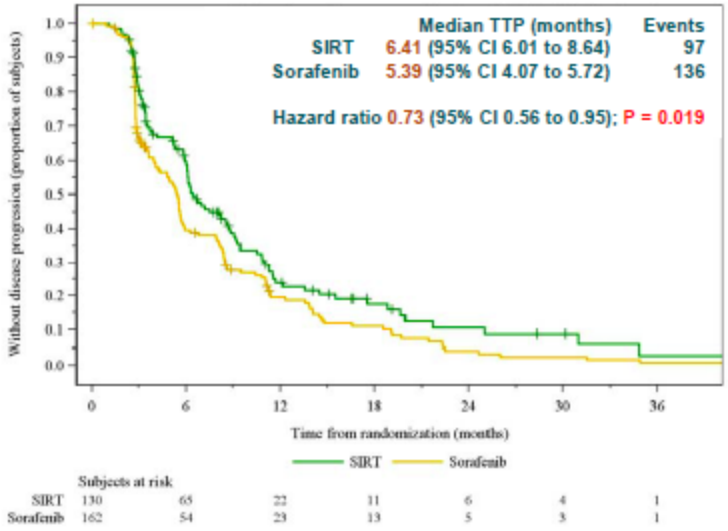


Efficacy: Time to Progression

- **Intent-to-treat population**



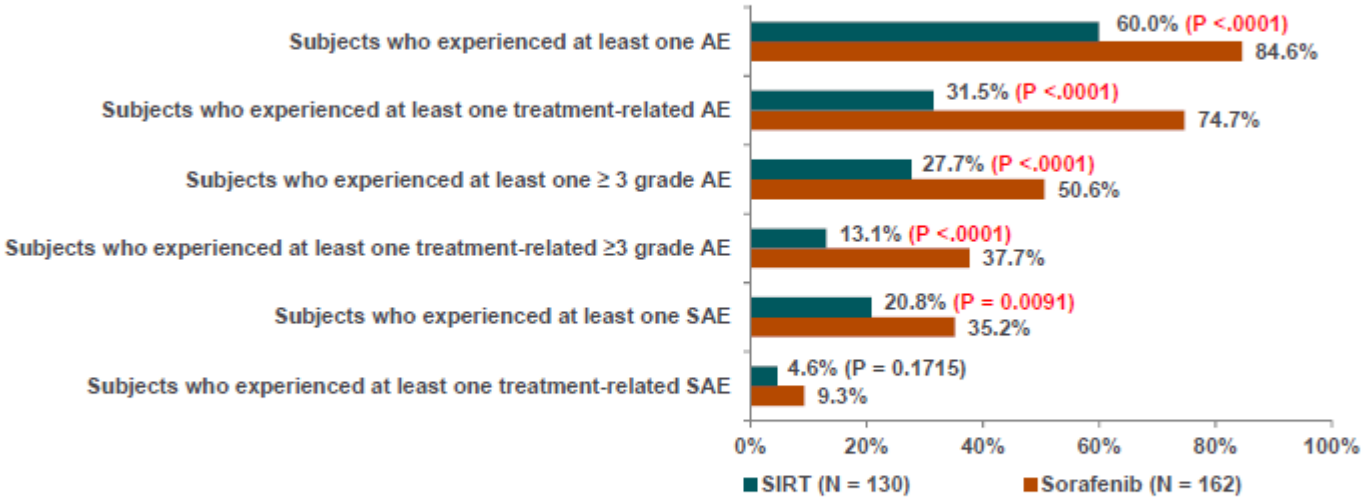
- **Treated population**



Efficacy: Secondary Outcomes

	Intent-to-treat population			Treated population		
	SIRT (N = 182)	Sorafenib (N = 178)	P-value	SIRT (N = 130)	Sorafenib (N = 162)	P-value
Time-to-tumor progression (months)						
Median	6.08	5.36		6.41	5.39	
Hazard ratio (95% confidence interval)	0.88 (0.69, 1.11)		0.287	0.73 (0.56, 0.95)		0.019
Time-to-tumor progression in liver (months)						
Median	6.11	5.39		6.77	5.45	
Hazard ratio (95% confidence interval)	0.87 (0.68, 1.10)		0.241	0.72 (0.55, 0.93)		0.013
Progression-free survival (months)						
Median	5.85	5.06		6.28	5.22	
Hazard ratio (95% confidence interval)	0.89 (0.71, 1.12)		0.306	0.73 (0.56, 0.93)		0.013
Progression-free survival in liver (months)						
Median	6.01	5.06		6.67	5.22	
Hazard ratio (95% confidence interval)	0.88 (0.70, 1.10)		0.259	0.71 (0.55, 0.92)		0.009

Overall Safety



Includes adverse events (AEs) and serious adverse events (SAEs) with onset date on or after study treatment start date. Treatment-related AE or SAE defined as those with certain, probable, possible, or missing relationship to study treatment. P values were computed for comparison between treatment arms using the Fisher's exact test.

Selected Adverse Events Graded with CTCAE 4.02

System Organ Class Preferred term, Number of subjects (%)	SIRT (N = 130) Grade 1 - 2	 Grade ≥ 3	Sorafenib (N = 162) Grade 1 - 2	 Grade ≥ 3	P Grade 1 - 2	 Grade ≥ 3
Blood and lymphatic system disorders						
Anaemia	4 (3.1)	0	5 (3.1)	4 (2.5)	1.0000	0.1315
Gastrointestinal disorders						
Abdominal pain	11 (8.5)	3 (2.3)	9 (5.6)	2 (1.2)	0.3585	0.6588
Ascites	5 (3.8)	5 (3.8)	14 (8.6)	4 (2.5)	0.1505	0.5179
Constipation	0	0	9 (5.6)	0	0.0051	-
Diarrhoea	2 (1.5)	0	42 (25.9)	6 (3.7)	<0.001	0.0353
Nausea	10 (7.7)	1 (0.8)	10 (6.2)	0	0.6466	0.4452
General disorders and administration site conditions						
Fatigue	5 (3.8)	0	19 (11.7)	6 (3.7)	0.0175	0.0353
Oedema peripheral	10 (7.7)	0	5 (3.1)	1 (0.6)	0.1082	1.0000
Pyrexia	6 (4.6)	0	17 (10.5)	1 (0.6)	0.0804	1.0000
Metabolism and nutrition and disorders						
Decreased appetite	11 (8.5)	0	20 (12.3)	1 (0.6)	0.3412	1.0000
Hypoalbuminaemia	6 (4.6)	1 (0.8)	7 (4.3)	1 (0.6)	1.0000	1.0000

Includes adverse events which were experienced by at least 5% of treated subjects in either arm and have onset date on or after study treatment start date. P values were computed for comparison between treatment arms using the Fisher's exact test.

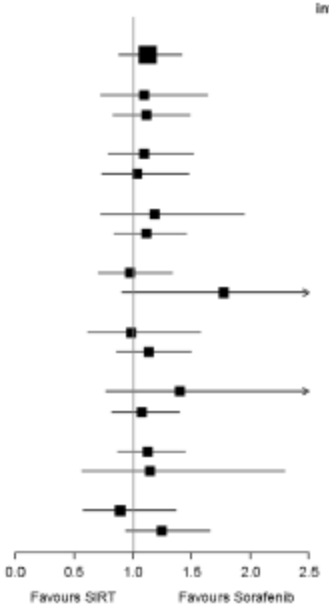
Selected Adverse Events Graded with CTCAE 4.02

System Organ Class Preferred term, Number of subjects (%)	SIRT (N = 130) Grade 1 - 2	 Grade ≥ 3	Sorafenib (N = 162) Grade 1 - 2	 Grade ≥ 3	P Grade 1 - 2	 Grade ≥ 3
Respiratory, thoracic and mediastinal disorders						
Cough	8 (6.2)	0	8 (4.9)	0	0.7969	-
Skin and subcutaneous tissue disorders						
Alopecia	0	0	16 (9.9)	0	<.0001	-
Palmar-plantar erythrodysaesthesia syndrome	1 (0.8)	0	62 (38.3)	27 (16.7)	<.0001	<.0001
Rash	0	0	18 (11.1)	0	<.0001	-
Vascular disorders						
Hypertension	0	0	22 (13.6)	2 (1.2)	<.0001	0.5043
AEs typically associated with SIRT						
Gastric ulcer	0	1 (0.8)	0	0	-	0.4452
Upper gastrointestinal haemorrhage	1 (0.8)	1 (0.8)	0	3 (1.9)	0.4452	0.6315
Jaundice	1 (0.8)	1 (0.8)	1 (0.6)	2 (1.2)	1.0000	1.0000
Hepatic cirrhosis	0	0	1 (0.6)	1 (0.6)	1.0000	1.0000
Portal hypertension	0	0	0	1 (0.6)	-	1.0000
Radiation hepatitis	0	2 (1.5)	0	0	-	0.1974

Includes adverse events which were experienced by at least 5% of treated subjects in either arm, or known to be associated with SIRT and have onset date on or after study treatment start date. P values were computed for comparison between treatment arms using the Fisher's exact test.

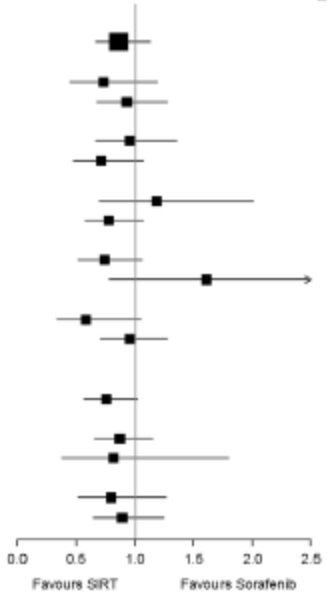
Subgroup Analysis (Intent-to-treat Population)

Subgroup	Events / No.of subjects	Median OS SIRT	Median OS Sorafenib	HR (95% CI)	P-value	P-value interaction
Overall survival (months)	266 / 360	8.84	10.02	1.12 (0.88, 1.42)	0.360	
Portal vein thrombosis						0.933
Yes	90 / 110	5.32	4.93	1.09 (0.72, 1.64)	0.698	
No	176 / 250	11.27	13.86	1.11 (0.83, 1.49)	0.491	
BCLC						0.822
B	141 / 209	11.70	13.86	1.09 (0.79, 1.52)	0.594	
C	123 / 149	6.97	5.98	1.03 (0.73, 1.48)	0.850	
Prior HCC treatment						0.829
Yes	62 / 95	13.34	14.39	1.18 (0.72, 1.95)	0.508	
No	204 / 265	7.56	9.07	1.11 (0.84, 1.46)	0.451	
Hepatitis						0.118
B	147 / 197	9.07	8.61	0.97 (0.70, 1.34)	0.864	
C	35 / 45	8.90	15.51	1.77 (0.90, 3.49)	0.098	
ECOG						0.618
0	198 / 276	9.07	12.12	0.98 (0.61, 1.58)	0.943	
1	68 / 84	8.54	7.98	1.13 (0.86, 1.50)	0.386	
Prior TACE						0.428
Yes	44 / 66	11.27	12.32	1.40 (0.77, 2.54)	0.273	
No	222 / 294	8.44	9.63	1.07 (0.82, 1.40)	0.603	
Child-pugh score						0.975
A	233 / 319	9.07	12.12	1.12 (0.87, 1.45)	0.371	
B	31 / 39	6.77	6.08	1.14 (0.56, 2.30)	0.719	
ALBI grade						0.204
1	81 / 118	11.79	13.86	0.89 (0.57, 1.37)	0.584	
2/3	184 / 241	8.02	9.03	1.24 (0.93, 1.66)	0.140	



Subgroup Analysis (Treated Population)

Subgroup	Events / No.of subjects	Median OS SIRT	Median OS Sorafenib	HR (95% CI)	P-value	P-value interaction
Overall survival (months)	218 / 292	11.27	10.41	0.86 (0.66, 1.13)	0.273	
Portal vein thrombosis						0.418
Yes	67 / 78	7.49	4.93	0.73 (0.44, 1.19)	0.204	
No	151 / 214	13.01	14.06	0.93 (0.67, 1.28)	0.641	
BCLC						0.296
B	122 / 178	13.50	14.09	0.95 (0.66, 1.36)	0.777	
C	94 / 112	9.17	5.82	0.71 (0.47, 1.07)	0.104	
Prior HCC treatment						0.196
Yes	54 / 83	14.29	14.98	1.18 (0.69, 2.01)	0.553	
No	164 / 209	9.46	9.03	0.78 (0.57, 1.07)	0.121	
Hepatitis						0.058
B	122 / 162	13.34	8.61	0.74 (0.51, 1.06)	0.102	
C	30 / 39	9.36	15.51	1.61 (0.78, 3.31)	0.194	
ECOG						0.150
0	170 / 233	11.70	12.22	0.58 (0.33, 1.05)	0.071	
1	48 / 59	11.27	7.98	0.95 (0.70, 1.28)	0.724	
Prior TACE						
Yes	37 / 56	11.27	Not est.			
No	181 / 236	10.78	9.63	0.76 (0.56, 1.02)	0.072	
Child-pugh score						0.888
A	191 / 259	11.33	12.22	0.87 (0.65, 1.15)	0.325	
B	26 / 32	9.46	6.08	0.82 (0.37, 1.80)	0.613	
ALBI grade						0.711
1	74 / 104	13.34	13.86	0.80 (0.51, 1.27)	0.352	
2/3	143 / 187	10.84	9.07	0.89 (0.64, 1.25)	0.511	



Conclusions

- The primary end point of the study was not met.
  - In this study SIRT was not shown to be superior to sorafenib with respect to overall survival
  - No statistically significant difference was demonstrated between SIRT and sorafenib

- However, patients treated with SIRT have
  - a significantly better tumor-response rate
  - significantly fewer total number of adverse events and severe adverse events

  when compared with those treated with sorafenib.

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