THE CUTTING EDGE OF MODERN MEDICINE
CIRSE 2020 SUMMIT SEPTEMBER 12-15 ONLINE

Short-term safety and quality of life outcomes following radioembolization in primary and secondary liver tumours: a multi-centre analysis of 200 patients in France

Romaric Loffroy, Maxime Ronot, Michel Greget, Antoine Bouvier, Charles Mastier, Christian Sengel, Lambros Tselikas, Dirk Arnold, Geert Maleux, Jean-Pierre Pelage, Olivier Pellerin, Bora Peynircioglu, Bruno Sangro, Niklaus Schaefer, María Urdániz, Nathalie Kaufmann, José Ignacio Bilbao, Thomas Helmberger, Valérie Vilgrain, On behalf of the CIRT-FR Principal Investigators

CIRT-FR Interim Analysis Results

Presented by Prof. Romaric Loffroy

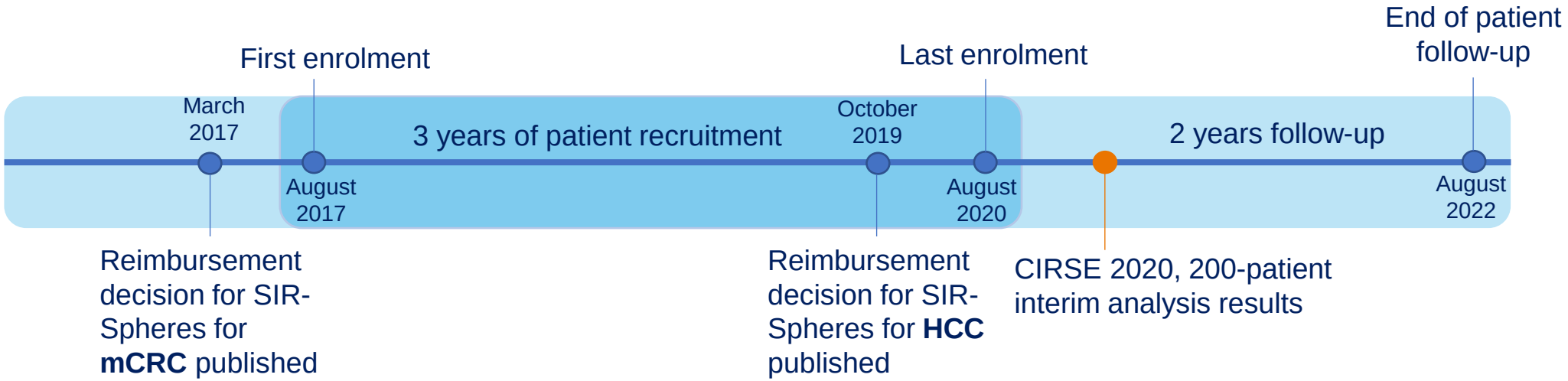
Monday, September 14 2020

CIRT-FR CIRSE Registry for SIR-Spheres Therapy in France

Conflict of interest

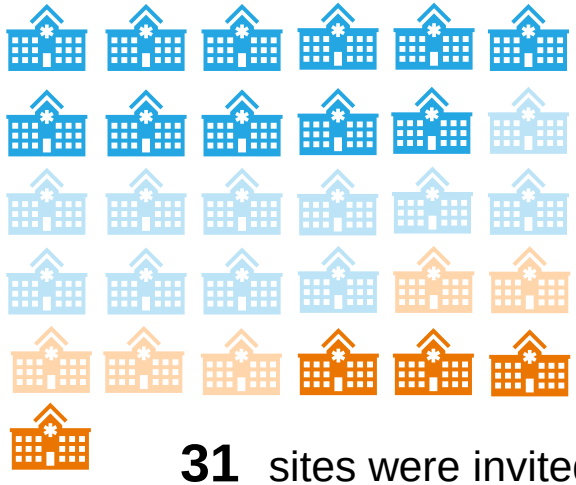
- Consultancy to SIRTEX Medical

200-patient interim analysis of the prospective, post-market, observational study CIRT-FR



- Exhaustively capture the real-life clinical practice of TARE, using SIR-Spheres yttrium-90 resin microspheres in **all patients** treated in France.
- Data will be used by the French National Authority for Health (HAS) to evaluate the **renewal of SIR-Spheres reimbursement** for patients with colorectal liver metastases and hepatocellular carcinoma.

Participating sites



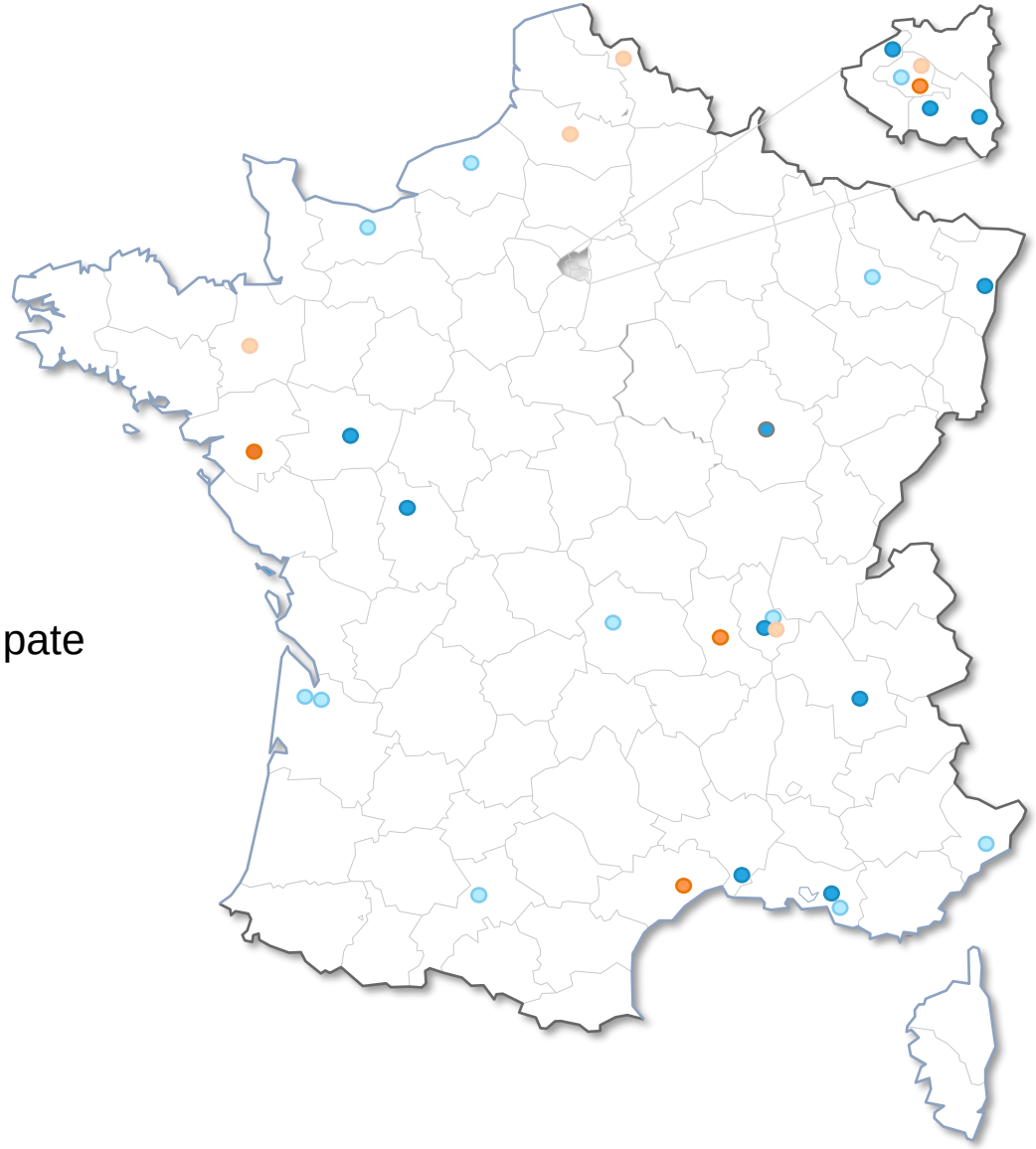
31 sites were invited to participate

22 participated

- **11** enrolling centres
- **11** not enrolling centres

5 contracting process

4 declined participation



Objectives

- **Primary objective:** to observe the real-life clinical application of TARE with SIR-Spheres Y-90 resin microspheres by means of 5 categories:

1. **First-line** TARE treatment with or without concomitant systemic therapy
2. **Second or subsequent line** TARE treatment with or without concomitant systemic therapy after previous first-line systemic therapy, including salvage therapy when no other systemic therapies used alone are likely to be efficacious
3. TARE treatment with or without concomitant systemic therapy **after previous interventional liver-directed procedures or liver surgery**
4. **Addition of TARE to systemic therapy** (any line) or to any other **treatment** (e.g. ablation) intended as part of a multimodal curative therapy with any of the following objectives: resectability and/or ablative therapy and/or transplantation
5. Treatment with TARE in patients **intolerant of chemotherapy** or patients considered not suitable for systemic therapy
6. Other

Objectives

- **Secondary objectives:** to assess baseline characteristics, safety and quality of life data.

Secondary objective	Endpoint	Measured according to
Safety	• Adverse events	• CTCAE 4.03
Quality of Life	• Global health score • Functional score • Symptomatic score • HCC Module	• EORTC QLQ-C30 Scoring Manual v 3.0 • EORTC QLQ-HCC18 Scoring Manual v 2.0

Results – Patient demographics

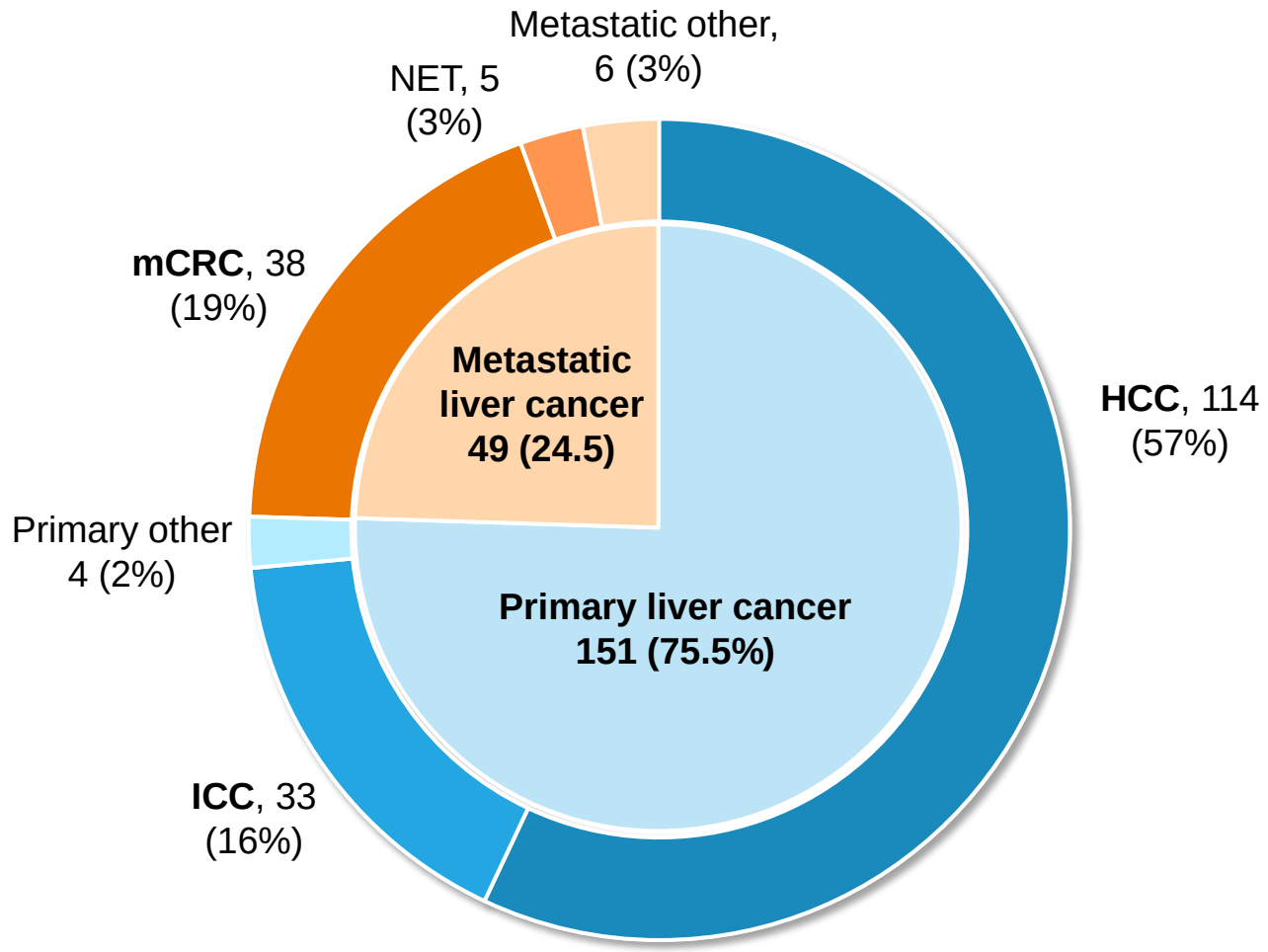
200 patients

treated between August 2017 and June 2020

- **Male, 140** (70%)
- **Age** (range 19-92), **median 66**

85% patient coverage in 22 centres

Quarterly case logs, determined that patient coverage of all patients treated at participating sites was 85% (when disregarding one centre, patient coverage was 91%)



Primary endpoint

Results of the three biggest groups representing 74.5% of the patients

First-line treatment

- **61** (30.5 %) patients underwent TARE with SIR-Spheres as a first-line treatment

HCC; 43/114, **37.7%** patients

ICC; 18/33, **54.5%** patients

mCRC; **0** patients

After previous procedures without previous chemotherapy

- **53** (26.5 %) patients received the treatment after **previous liver-directed interventional radiological procedures** or liver surgery in the absence of prior chemotherapy and post hepatic procedures

HCC; 50/114, **43.8%** patients

ICC; 1/33, **3%** patients

mCRC; 2/38, **5.2%** patients

After previous procedures

- **35** (17.5 %) patients received TARE treatment after **previous first-line** systemic therapy

HCC; 7/114, **6.1%** patients

ICC; 8/33, **24.2%** patients

mCRC; 20/38, **52.6%** patients

Safety - Results per patient

Number of patients with at least one AE n=200	peri-interventional		<30days		>30days	
	Overall	Grade 3 or 4	Overall	Grade 3	Overall	Grade 3 or 4
	8 (4%)	4 (2%)	24 (12%)	3 (1.5%)	122 (61%)	28 (14%)

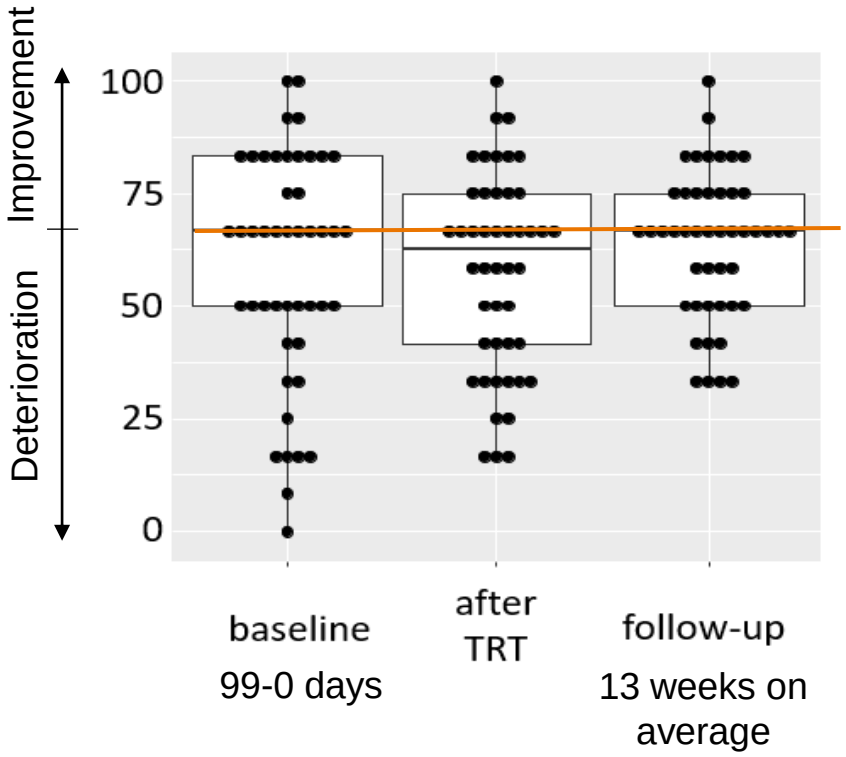
- 30 day mortality: 1%
- 170 (44.5%) AEs were ungraded

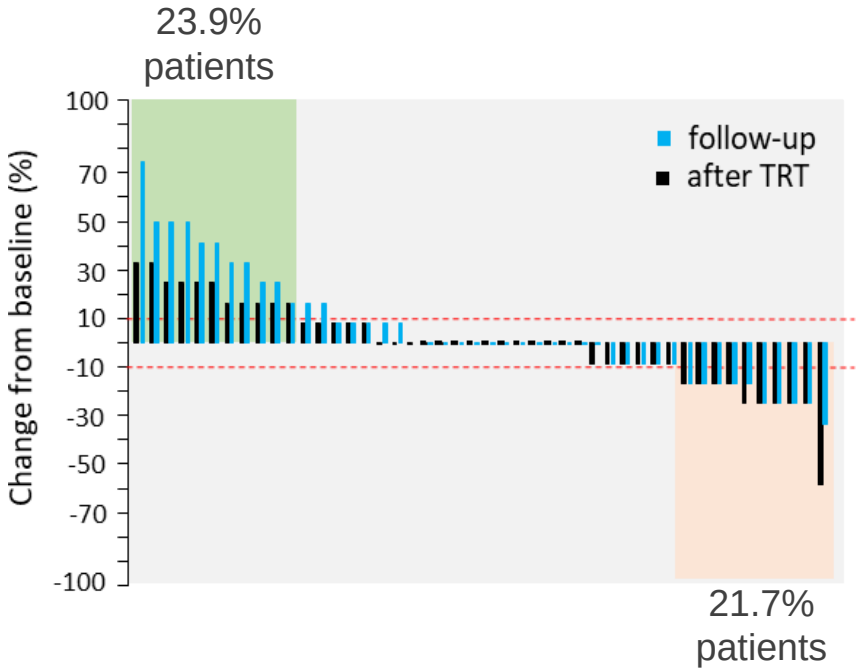
Safety – Overall results

	peri-interventional AEs		<30days		>30days	
	Overall AE n=9 (%)	AEs Grade 3 or 4 n=5 (%)	Overall AE n=42 (%)	AEs Grade 3 n=6 (%)	Overall AE n=382 (%)	AEs Grade 3 or 4 n=33(%)
Abdominal pain	4 (44.4)	4 (80)	2 (4.8)	-	50 (13.1)	4 (12.1)
Fatigue	-	-	11 (26.2)	-	91 (23.8)	8 (24.2)
Fever	-	-	-	-	9 (2.4)	-
Nausea	-	-	4 (9.5)	-	14 (3.7)	-
Vomiting	1 (11.1)	1 (20)	4 (9.5)	-	6 (1.6)	1 (3.0)
RE Induced Gastritis	-	-	1 (2.4)	-	-	-
Gastritis	-	-	-	-	2 (0.5)	-
RE Induced GI Ulceration	-	-	1 (2.4)	-	-	-
GI Ulceration	-	-	1 (2.4)	1(16.7)	3 (0.8)	2 (6.1)
REILD	-	-	2 (4.8)	2 (33.3)	-	-
Radiation Pneumonitis	-	-	-	-	-	-
Radiation Cholecystitis	-	-	-	-	-	-
Radiation Pancreatitis	-	-	-	-	-	-
Other	4 (44.4)	-	16 (38.1)	3 (50)	207 (54.1)	18 (54.5)

Results – Quality of Life (EORTC QLQ-C30)

Global health score for **46** (23%) patients remains relatively constant when compared to baseline

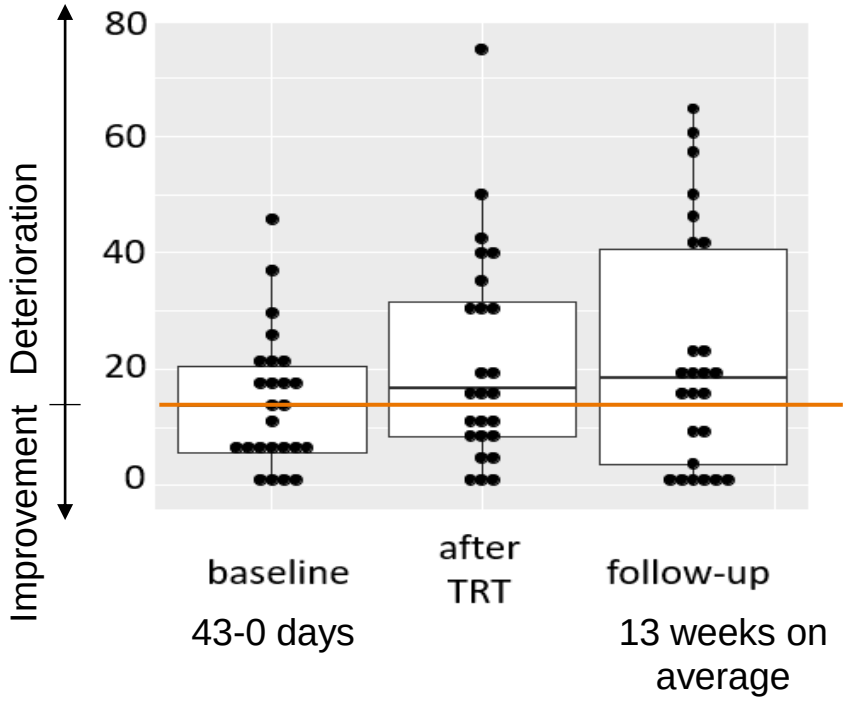


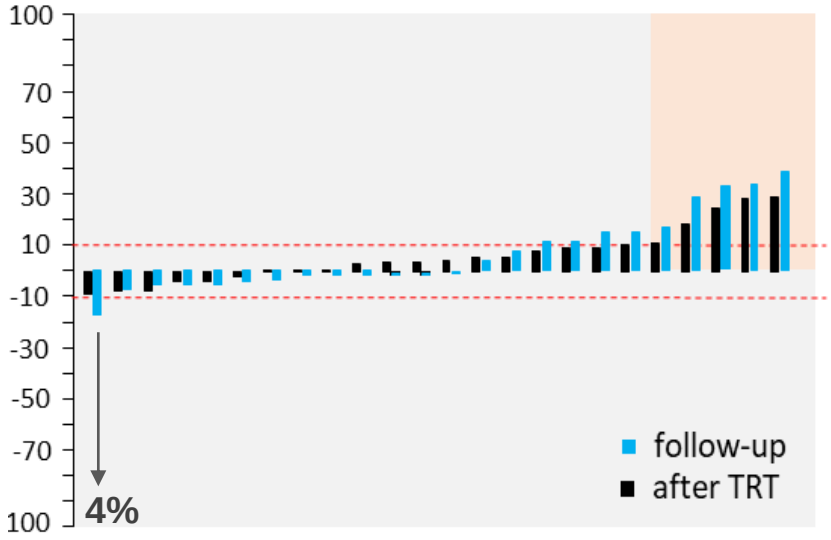


*Results for functional and symptom score were similar to those shown for global health

Results – Quality of Life HCC18 Module

HCC 18 Score for **25** (22%) HCC patients worsened during treatment and 1st follow-up when compared to baseline





- Follow-up: change from baseline to follow-up, **36%** of the patients
- After TRT: change from baseline to TRT, **20%** of the patients

Discussion and Limitations

Representativeness
CIRT-FR constitutes a representative study on the real-life application of TARE using SIR-Spheres in France - 85% of all patients treated were included in the study.

Safety
TARE can be considered as a safe treatment alternative.

HRQOL
HRQOL remains relatively constant when compared to baseline.
HRQOL observed in controlled trials holds true to the real-life clinical practice.

Limitations
High number of ungraded AEs: 44.5%.
Only 23% of patients provided HRQOL data for all three timepoints required.
More than half of all patients were provided by a single centre.

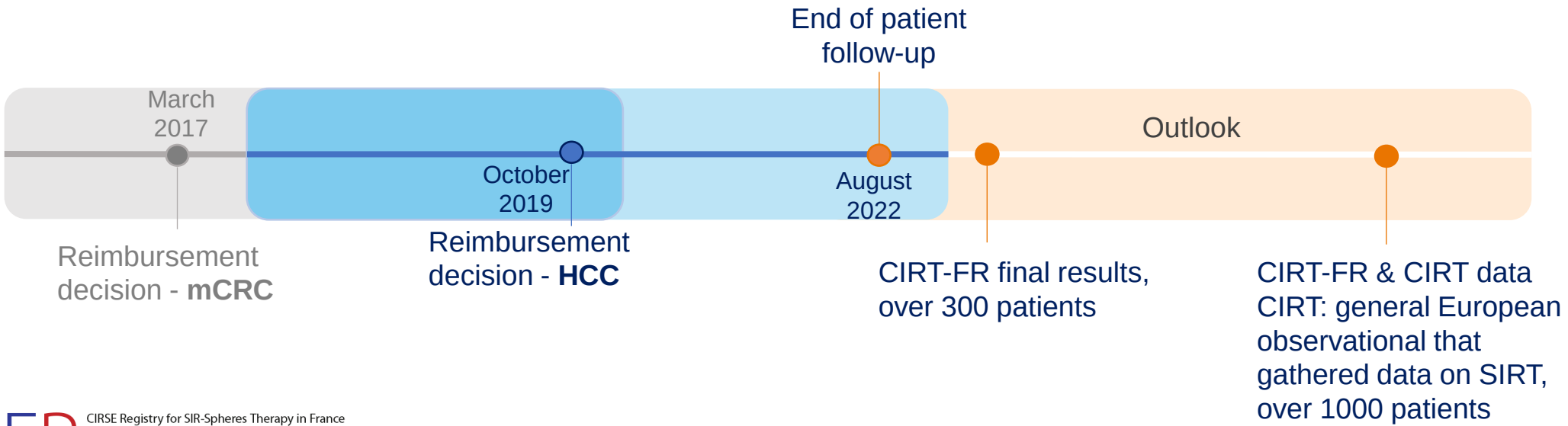
Conclusion and Outlook

Comparison to previous data

Safety and quality of life generated by randomised-controlled trials is reflected when assessing the real-world application of TARE in this interim analysis.

Reimbursement impact

Reimbursement is not a deciding factor for treatment administration when a treatment is considered clinically effective.



Acknowledgements

- Patients and local site staff
- CIRT-FR investigators
- SIRTEX Medical Europe GmbH
- Dr. Carole Déan
- ConexSys Inc
- ITEA GmbH

Thank you!

more information in CVIR

“Short-term safety and quality of life outcomes following radioembolization in primary and secondary liver tumours: a multi-centre analysis of 200 patients in France”