**ASX / MEDIA RELEASE** **1st June 2015**

# ASCO Peer Review Supports the Benefits of SIR-Spheres® Y-90 Resin Microspheres in the Liver

- SIRFLOX results confirmed as both statistically significant and clinically meaningful in the liver
- Anticipate first-line utilisation in metastatic colorectal cancer
- SIRFLOX study selected by ASCO as one of the "Best of ASCO" presentations

**Sydney, Australia; 1st June 2015** – Sirtex Medical Limited (ASX:SRX) is pleased to announce that following the ASCO presentation and peer review process of the SIRFLOX study, the results have been well accepted by the medical oncology community. The feedback from Key Opinion Leaders (KOLs) has been positive, and to that extent Sirtex believes sales in first-line mCRC are achievable based on the strong results demonstrated in the liver.

Sirtex anticipates increased utilisation of SIR-Sphere Y-90 resin microspheres in the first-line setting will gain momentum over time. SIRFLOX is the first ever study with Level 1 evidence to show a liver-directed therapy in combination with systemic chemotherapy and a biologic agent produces a clinically meaningful and significant effect in the liver. Consequently, incorporation into clinical practice beyond the current salvage setting in mCRC is now a realistic possibility with continued education of the results to the medical oncology community.

"We are pleased with the outcome of the ASCO peer review process, which we believe will ultimately facilitate an increase in the utilisation of SIR-Spheres microspheres at an earlier stage of patient treatment. Accordingly, we will continue to implement our regulatory and reimbursement strategies, progress discussions with treatment guideline panels and seek further KOL endorsement of the SIRFLOX results. Meanwhile, our current salvage business continues to perform strongly," commented Mr Gilman Wong, CEO of Sirtex Medical.

With a 7.9 month improvement in Progression-Free Survival (PFS), a 31% lower risk of progression (HR=0.69) and strong statistical significance (p=0.002) achieved in the liver, Associate Professor Peter Gibbs, co-principal investigator of the SIRFLOX study and Consultant Medical Oncologist, The Royal Melbourne Hospital said "This finding matters a great deal because the liver is almost invariably the organ where colorectal cancer spreads to first. While half the patients initially diagnosed with colorectal cancer survive thanks to surgical removal of the primary tumour before the disease has spread elsewhere in the body, liver metastases eventually cause the death of the majority of the remaining hundreds of thousands of patients each year whose tumours spread but are inoperable."

Professor Eric Van Cutsem, MD PhD from the University of Leuven, Belgium and current European Organisation for Research and Treatment of Cancer (EORTC) board member said "The SIRFLOX study results provide robust Level 1 evidence for medical oncologists to incorporate in their daily clinical practice."

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ASCO has further indicated the potential clinical relevance of the SIRFLOX study by selecting it as a "Best of ASCO" presentation being one of just 71 of the several thousand abstracts reviewed for this meeting. "Best of ASCO" papers may be discussed in an ongoing cascade of official follow-up presentations that national oncology leaders will deliver over the coming months to medical oncologists in their countries who were unable to attend the ASCO Congress in Chicago.

A copy of the full Sirtex Media release from the ASCO meeting can be viewed at the following link: http://sirtex.com/au/newsroom/

**Sirtex will host an investor conference call at 9:00 a.m. today following the release of the SIRFLOX Results Investor Presentation to the ASX, with details shown below.**

**Conference ID:** 5246 3798

**Toll Free Dial-in Details:**

Australia Toll Free: 1800 123 296
Australia Local Dial: +61 2 8038 5221

USA: 1855 293 1544
Hong Kong: 800 908 865
Singapore: 800 616 2288
United Kingdom: 0808 234 0757
New Zealand: 0800 452 782
Canada: 1855 5616 766
Japan: 0120 985 190

**About ASCO**

The ASCO Annual Meeting brings together 30,000 oncology professionals from around the world. Educational sessions feature world-renowned faculty discussing state-of-the-art treatment modalities, new therapies, and ongoing controversies in the field. Science sessions present the latest ground-breaking research in oral and poster format. Sirtex will have an exhibit booth **(#10135)** at the ASCO Annual Meeting from 29th May to 2nd June.

**About SIRFLOX**

The SIRFLOX study is an international, multi-centre, randomised controlled study that enrolled over 500 patients with mCRC whose disease was non-resectable and had spread to either the liver alone or the liver plus a limited number of sites outside the liver, including lymph nodes and the lungs. The study was conducted in more than 100 hospitals across Australia, Europe, Israel, New Zealand and the United States. SIRFLOX is the first, large randomised controlled study that has examined the use of Selective Internal Radiation Therapy (SIRT, also known as radioembolisation) in the treatment of colorectal liver metastases. For more information, please visit www.sirflox.com and the ASX announcement made by Sirtex on 9th October 2014.

**About SIR-Spheres® Y-90 Resin Microspheres**

SIR-Spheres Y-90 resin microspheres are a medical device used in interventional oncology to deliver Selective Internal Radiation Therapy or SIRT (also known as radioembolisation), a proven technology for inoperable liver tumours that delivers substantial, targeted doses of radiation directly to the cancer.

Key SIR-Spheres Y-90 resin microspheres regulatory approvals include Pre-Market Approval (PMA) from the US FDA, European Union (CE Mark) approval and Australian TGA approval.

**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 called SIR-Spheres® Y-90 resin microspheres. Approximately 50,000 doses have been supplied to treat patients with liver cancer at more than 800 medical centres in over 40 countries. For more information please visit www.sirtex.com.

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# Sirtex Medical Limited (ASX:SRX)

**ASCO Presentation of SIRFLOX Study Results**

**Mr Gilman Wong, CEO**

**Mr Darren Smith, CFO**

**Dr David Cade, CMO**

**1st June 2015**

# Agenda

1. Introduction
2. SIRFLOX Study Presentation
3. Synopsis of Discussant and Expert Panel Discussion
4. Key Opinion Leader (KOL) Feedback
5. Conclusions and Outlook
6. Investor Q&A

# Introduction

- **SIRFLOX is the largest ever randomised, multi-centre, clinical study involving SIR-Spheres® Y-90 resin microspheres, a liver-directed therapy, in patients with liver-only or liver-dominant metastatic colorectal cancer (mCRC), and the largest interventional oncology study ever conducted**
  - Preliminary results announced 17th March
  - Selection of SIRFLOX study as an Oral Presentation announced 21st April
  - Publication of Oral Abstract announced 14th May
  - Oral Abstract Presentation by A/Prof. Peter Gibbs occurred on 30th May
- **The presentation of the SIRFLOX study results at the American Society of Clinical Oncology (ASCO) Annual Meeting was important**
  - Completes the ASCO peer review and validation process of the study
  - Drives submission of the study to a leading scientific journal for publication
  - Enables Sirtex to better understand the clinical importance of the results among the medical oncology community and hence the commercial potential

# SIRFLOX Study Presentation

## SIRFLOX: Randomized phase III trial comparing first-line mFOLFOX6 (+bevacizumab) *versus* mFOLFOX6 (+bevacizumab) + selective internal radiation therapy (SIRT) in patients with metastatic colorectal cancer

Peter Gibbs [(1)], Volker Heinemann, Navesh K. Sharma, Michael P. N. Findlay, Jens Ricke, Val Gebski, Mark Van Buskirk, Guy A. Van Hazel, on behalf of the SIRFLOX Study Group

(1) The Royal Melbourne Hospital, Melbourne, Australia

## Disclosure Information

Peter Gibbs

- Consultant or Advisory Role: Sirtex, Bayer, Alchemia, Sysmex Inostics, Ventana Medical, Roche, Amgen, Sanofi, Merck
- Research Funding: Roche, Amgen, Sanofi, Merck, Bayer, Ventana Medical, Sysmex Inostics

# SIRFLOX Study Presentation

## Background

- The combination of chemotherapy plus a biologic is standard first-line therapy for mCRC treated with palliative intent
- Liver metastases are the dominant site of disease in mCRC and the dominant cause of death
- Several decade history of evolving liver-directed therapies (HAC, cTACE, DEB-TACE, ablation, SBRT, SIRT)
  - No large Phase III RCTs to date, therefore uncertain clinical utility
- SIRFLOX is the first large Phase III RCT of a liver-directed therapy



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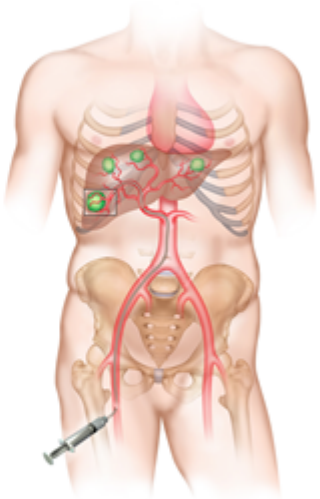
# SIRFLOX Study Presentation

## Selective Internal Radiation Therapy (SIRT)

- SIRT employs Yttrium-90 (Y-90) labelled resin microspheres as a liver-directed therapy [1]
  - Hepatic artery injection
  - Delivers a single large radiation dose to liver tumors
  - Radiation deposited over 3 weeks
  - FDA approved in 2002 for unresectable CRCLMs [2]
- Combining SIRT with first-line chemotherapy may improve control of CRC liver metastases and thereby improve overall survival [3, 4]




1. Kennedy A *et al. Int J Radiat Oncol, Biol Phys* 2007;68:13–23.
2. Colorectal cancer liver metastases.
3. Van Hazel *et al. J Surg Oncol* 2004;88:78–85.
4. Sharma *et al. J Clin Oncol* 2007;25:1099–106.

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# SIRFLOX Study Presentation

## SIRT using Y-90 Resin Microspheres [1] in mCRC

### Chemotherapy refractory setting

- RCT of 5FU *vs.* 5FU + SIRT showed improved Time to Liver Progression (HR: 0.38, *p*=0.003) [2]

### First-line setting

- RCT of 5FU/LV *vs.* 5FU/LV + SIRT showed improved Overall Survival (HR: 0.33, *p*=0.025) [3]
- Phase I study of FOLFOX4 + SIRT [4]
  - Established oxaliplatin MTD as 60 mg/m$^2$ for Cycles 1 – 3
  - Grade 3/4 neutropenia was the DLT


1. SIR-Spheres® microspheres, Sirtex Medical Limited, Sydney, Australia.
2. Hendlisz *et al. J Clin Oncol* 2010;28:3687–94.
3. Van Hazel *et al. J Surg Oncol* 2004;88:78–85.
4. Sharma *et al. J Clin Oncol* 2007;25:1099–106.




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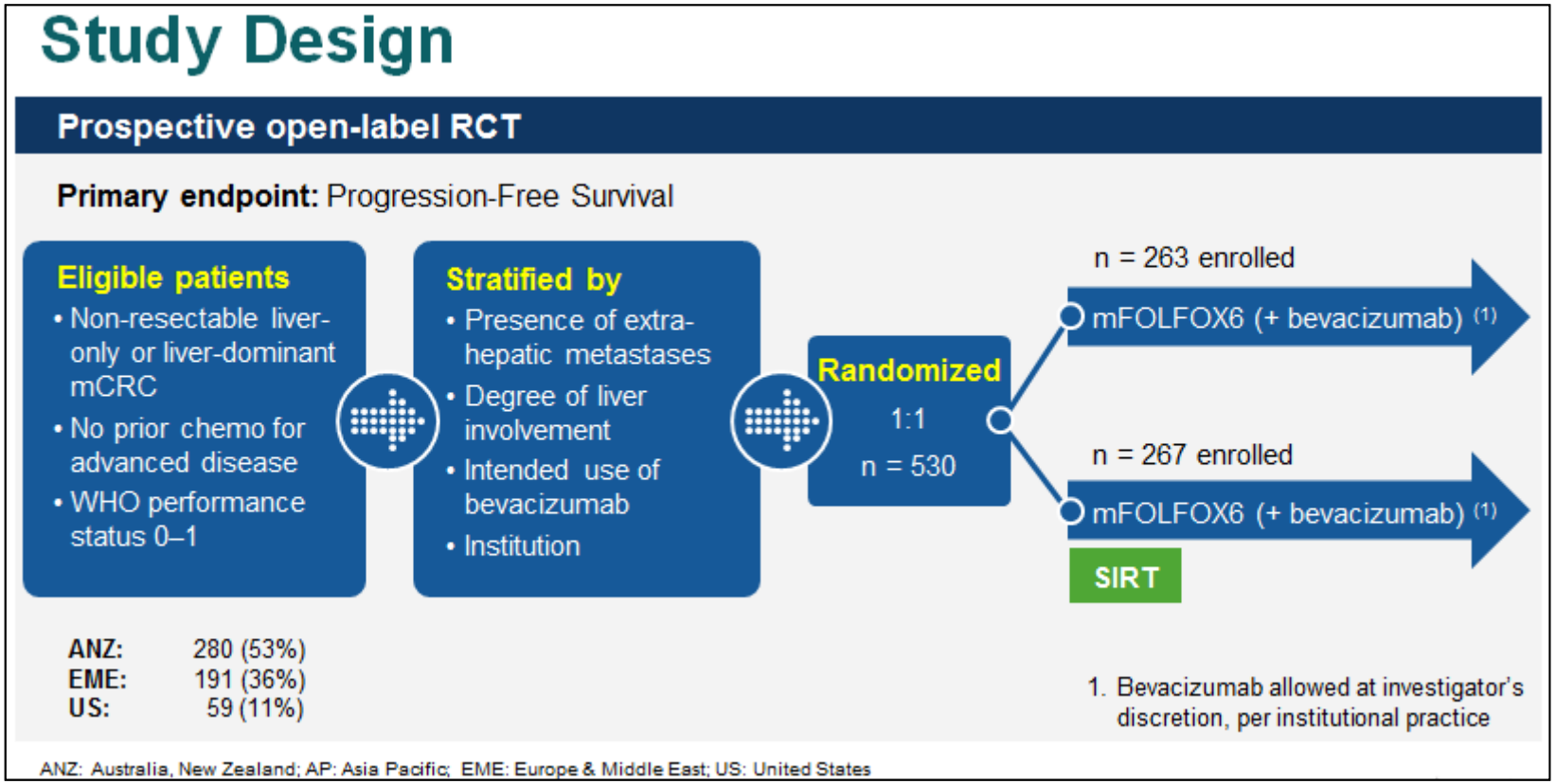
# SIRFLOX Study Presentation

## SIRFLOX is the first of three RCTs in a pre-planned combined analysis of impact on Overall Survival

| Study Name | Study Design | Geographic Region [1] | Recruitment Completed | Patients Recruited | OS Data Expected |
|---|---|---|---|---|---|
| **SIRFLOX** | RCT [2] | ANZ, EME, US | April 2013 | 530 | **2017** |
| **FOXFIRE** | RCT [2] | UK | November 2014 | 364 | |
| **FOXFIRE Global** | RCT [2] | ANZ, AP, EME, US | January 2015 | 209 | |
| | | | **Total accrual** | **1,103** | |

1. ANZ: Australia, New Zealand; AP: Asia Pacific; EME: Europe & Middle East; UK: United Kingdom; US: United States
2. FOLFOX-based (+ biologic) *vs.* FOLFOX-based (+ biologic) + SIRT

# SIRFLOX Study Presentation



# SIRFLOX Study Presentation

## Key Eligibility Criteria

- Adenocarcinoma of the colon or rectum
- Liver metastases not surgically resectable or ablatable (determined by local MDT)
- Limited extra-hepatic metastases allowed (protocol specific definition, by CT scan)
  - Up to 5 lung metastases ≤1 cm
  - Lymph nodes <2 cm in 1 anatomic region (chest, abdomen, or pelvis)
- WHO Performance Status 0 – 1
- No evidence of ascites, cirrhosis, portal hypertension, main portal vein tumor involvement or portal vein thrombosis
- No prior chemo except for adjuvant chemo completed ≥6 months prior



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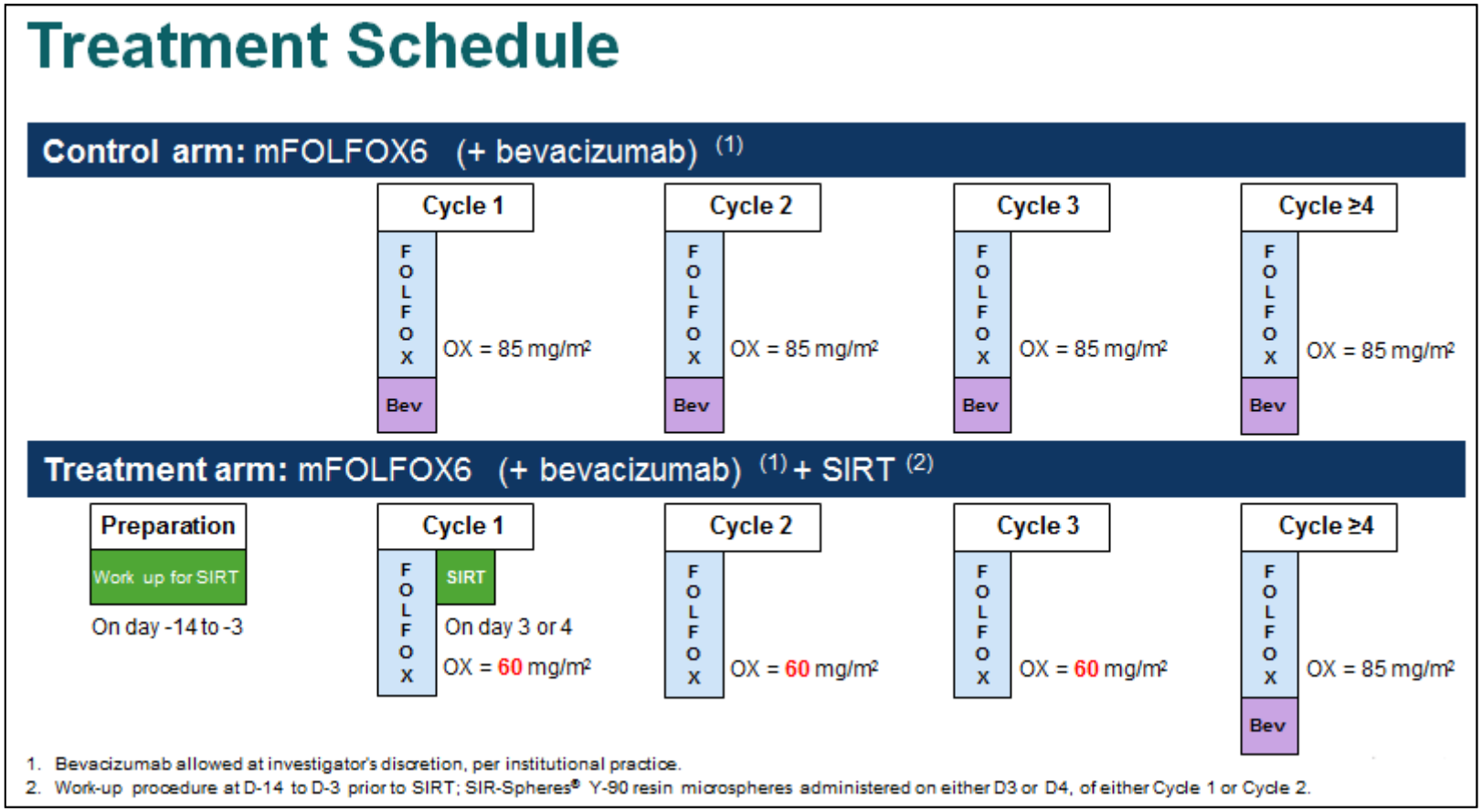
# SIRFLOX Study Presentation



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# SIRFLOX Study Presentation

## Study Endpoints

**Primary endpoint**

- PFS in the ITT population
  (with subsequent independent central imaging review)

**Secondary endpoints**

- PFS in the liver
- Tumor response rate in the liver
- Tumor response rate at any site (RECIST 1.0)
- Hepatic resection rate
- Toxicity & safety (NCI CTCAEv3.0)
- Health-related quality of life
- Overall survival, in a pre-planned combined analysis



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# SIRFLOX Study Presentation

## Statistical Plan

- Sample size calculation
  - Increase median PFS from 9.4 months in the control arm to 12.5 months
  - Corresponding to a 25% relative risk reduction (Hazard Ratio: 0.75)
  - 80% power and a two-sided alpha of 0.05
- Expected 438 (86%) events in 510 patients
- Enrollment restricted to ≤40% of patients with extra-hepatic metastases
- PFS in the liver analyzed by Competing Risk analysis [1] to account for the competing risks of
  1. First progression occurring outside the liver – as this may alter the course of the disease including the impact of subsequent therapy on liver metastases
  2. Death

1. Fine JP, Gray RJ. *J Am Stat Assoc* 1999;94:496–509.



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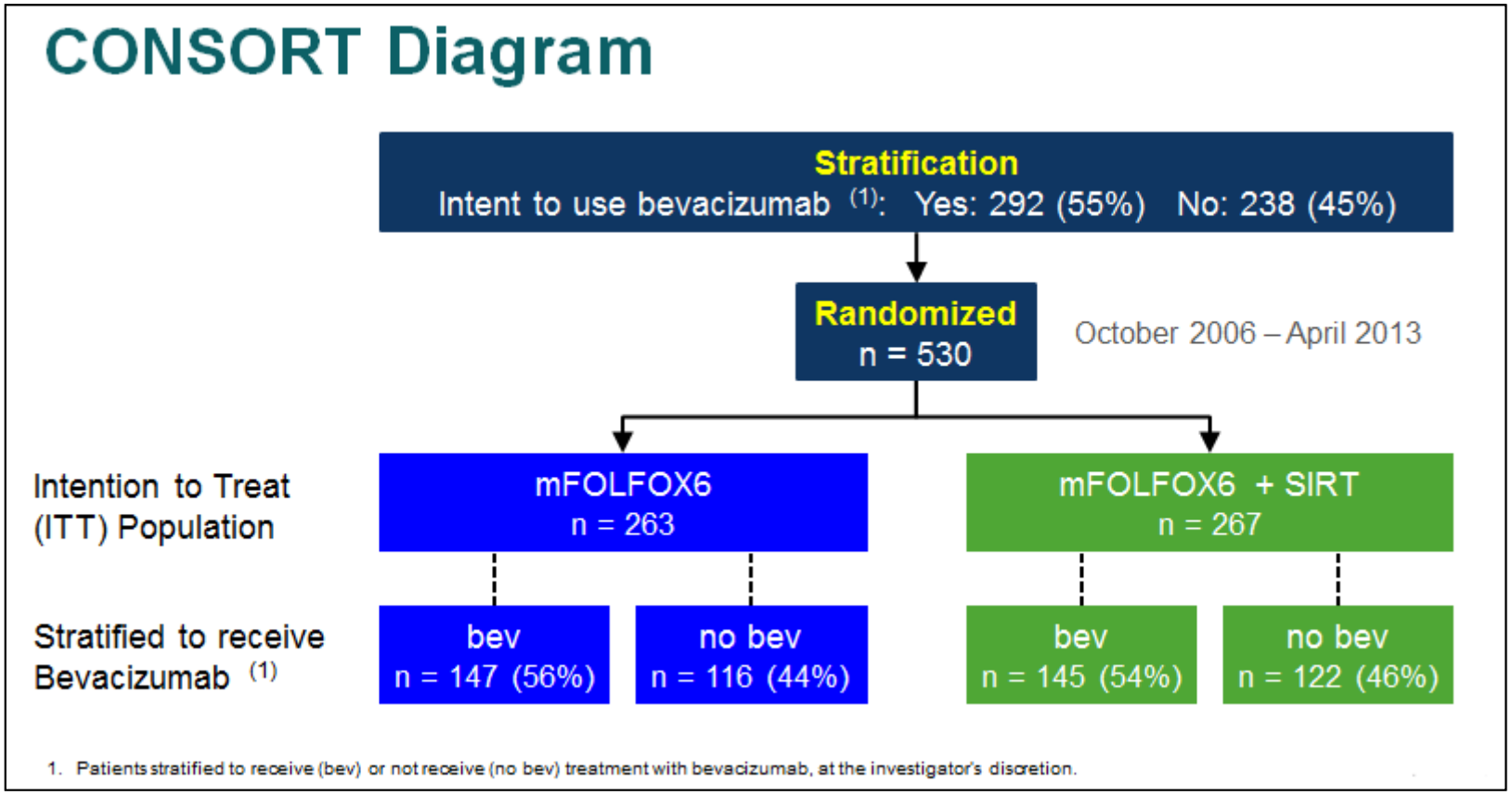
# SIRFLOX Study Presentation



# SIRFLOX Study Presentation

## Patient Characteristics in the ITT Population

| Characteristic | | FOLFOX (+ bev) (n = 263) | FOLFOX (+ bev) + SIRT (n = 267) |
|---|---|---|---|
| Age, years, median (range) | | 63 (23 – 89) | 63 (28 – 81) |
| Sex | Female | 88 (34%) | 85 (32%) |
| | Male | 174 (66%) | 182 (68%) |
| WHO performance status | 0 | 175 (67%) | 176 (66%) |
| | 1 | 87 (33%) | 90 (34%) |
| Extra-hepatic metastases | | 104 (40%) | 108 (40%) |
| Primary tumor not removed | | 121 (46%) | 119 (45%) |
| Synchronous metastases | | 233 (89%) | 241 (90%) |



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# SIRFLOX Study Presentation

## Treatment Characteristics

| Characteristic | | FOLFOX (+ bev) (n = 263) | FOLFOX (+ bev) + SIRT (n = 267) |
|---|---|---|---|
| Did not receive SIRT | | – | 18 (7%) |
| • Performance status compromise / SAEs / disease progression | | – | 6 (2%) |
| • Aberrant vascular anatomy | | – | 5 (2%) |
| • Procedural complication (vascular spasm, dissection, contrast agent) | | – | 4 (1%) |
| • Other reasons | | – | 2 (1%) |
| • Withdrew consent | | – | 1 (0.4%) |
| No treatment on study | | 11 (4%) | 3 (1%) |
| • Withdrew consent [1] | | 10 (4%) | – |
| • Performance status compromise / SAEs / disease progression | | – | 3 (1%) |
| • Lost to follow up | | 1 (0.4%) | – |
| Cycles of 5FU: | Median (IQR) [2] | 12 (9) | 12 (9) |
| Cycles of oxaliplatin: | Median (IQR) | 10 (4) | 10 (5) |
| Cycles of bevacizumab: [3] | Median (IQR) | 13 (11) | 8 (8) |

1. Including patients who may have received treatment off protocol.
2. Interquartile Range.
3. In patients with ITT for bevacizumab



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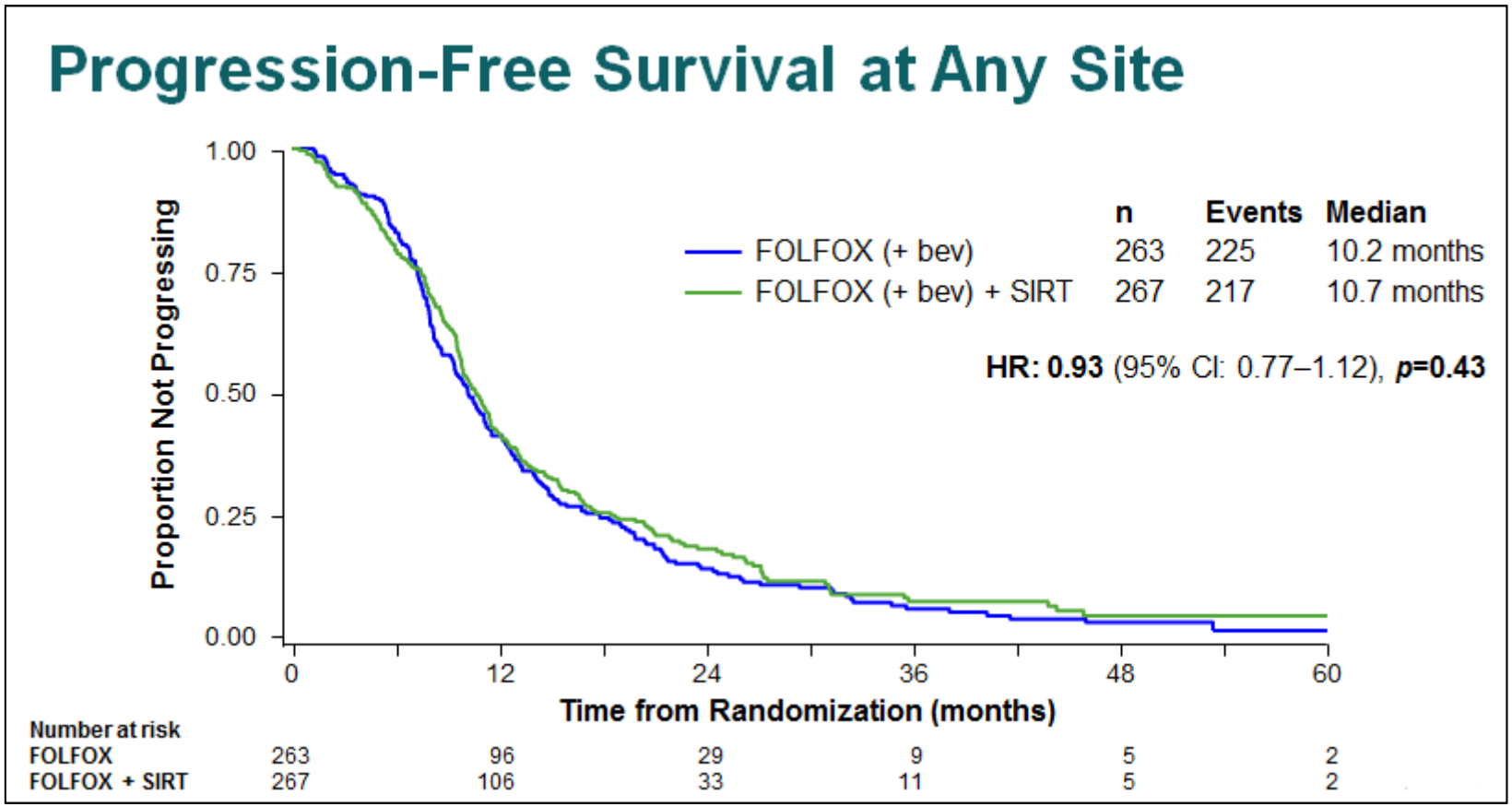
# SIRFLOX Study Presentation



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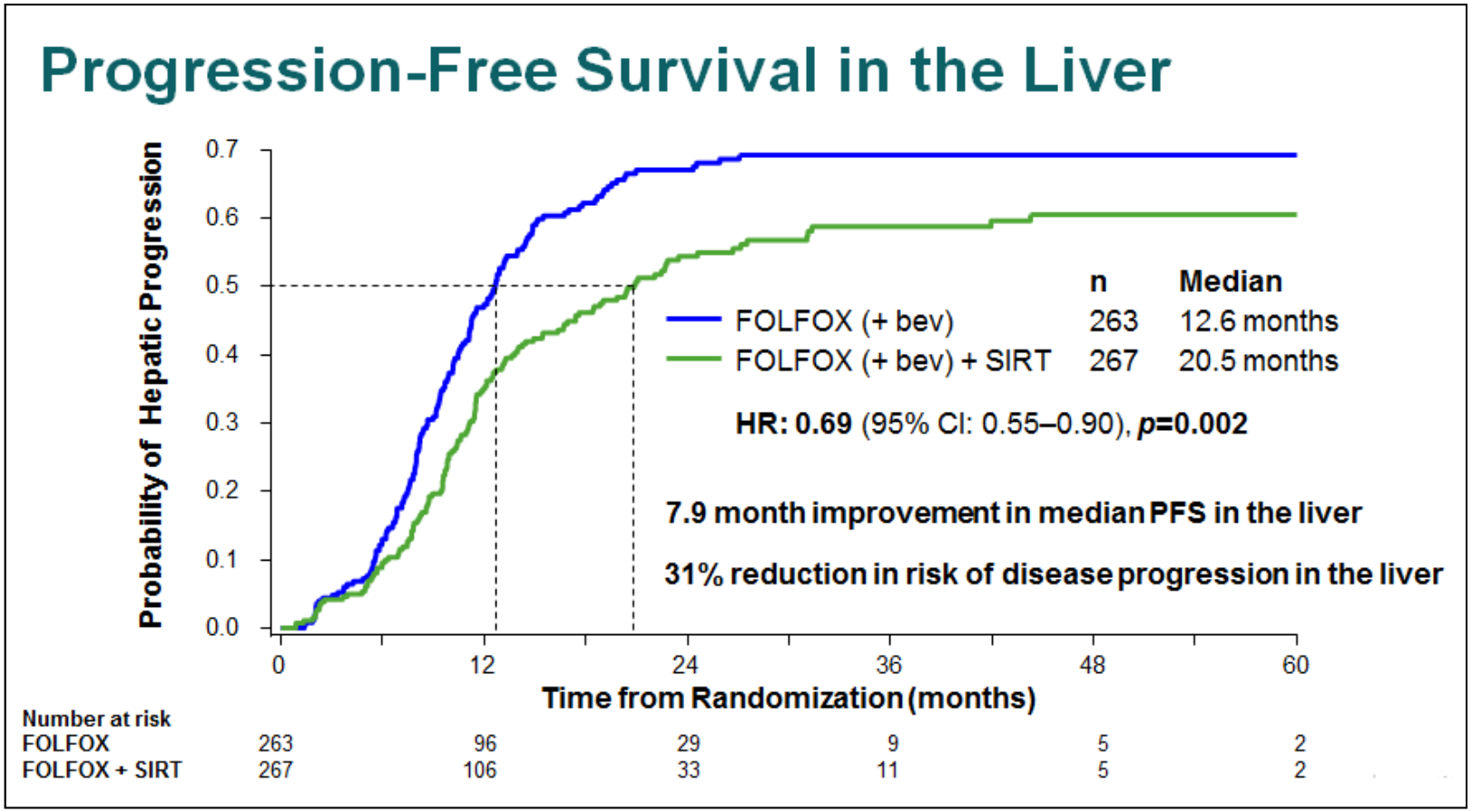

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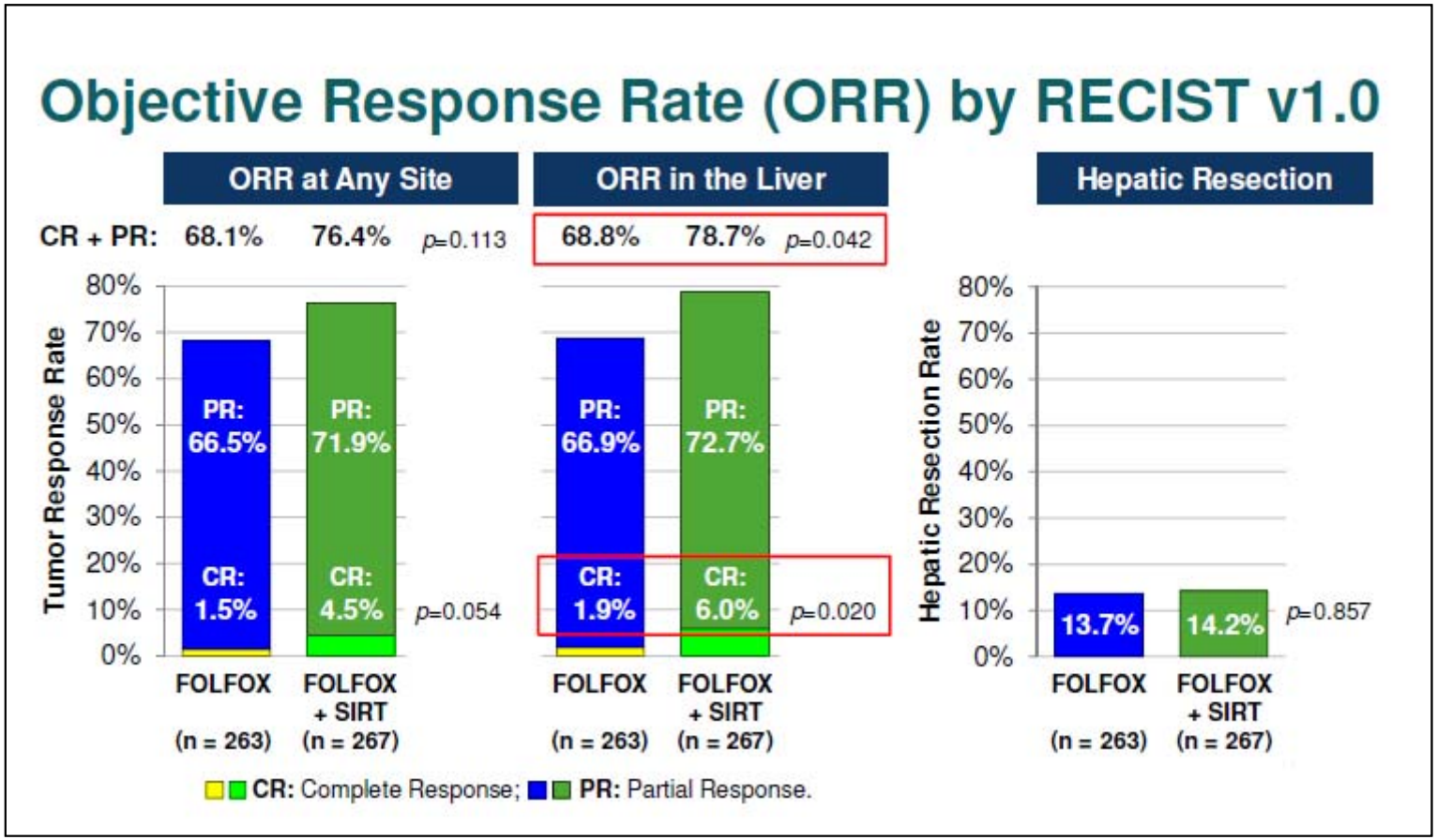




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# SIRFLOX Study Presentation

## Selected [1] All-Cause Grade ≥3 Adverse Events

| Events (all-causality) | FOLFOX (+ bev) (n = 270) Grade ≥3 (%) | FOLFOX (+ bev) + SIRT (n = 246) Grade ≥3 (%) |
|---|---|---|
| **All patients** | **73.4** | **85.4** |
| **Grade 5 events** | **1.9** | **3.7** |
| **Chemotherapy-associated events** | | |
| Neutropenia | 28.5 | 40.7* |
| Febrile neutropenia | 1.9 | 6.1* |
| Thrombocytopenia | 2.6 | 9.8* |
| Diarrhea | 8.9 | 7.3 |
| Nausea and/or vomiting | 4.1 | 8.1 |
| **SIRT-associated events** | | |
| Gastric or duodenal ulcer | 0 | 3.7* |
| Ascites | 0 | 2.8* |
| Hepatic failure | 0 | 1.2 |
| Radiation hepatitis | 0 | 0.8 |

* Denotes statistically significant difference in incidence of the adverse event.



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# SIRFLOX Study Presentation

## Conclusions

- Liver metastases are the dominant site of disease in mCRC and the dominant cause of death
- The addition of SIRT, using Y-90 resin microspheres, to FOLFOX-based first-line chemotherapy in patients with liver-dominant metastases:
  - Did not improve overall PFS, but achieved
  - A 7.9 month improvement in median PFS in the liver, representing a 31% reduction in risk of disease progression in the liver [HR: 0.69; *p*=0.002] with
    - No negative impact on duration of systemic therapy and
    - Had toxicities that were acceptable and as predicted



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# SIRFLOX Study Presentation

## Future Analyses

- Sub-groups of interest (liver only / liver dominant; effect of bevacizumab)
- Depth of response
- Quality of life
- Cost-effectiveness analysis
- Overall survival
  - Pre-planned combined analysis with **FOXFIRE** and **FOXFIRE Global** studies in >1,100 patients



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# SIRFLOX Study Presentation


## Acknowledgements

The authors thank

- The patients who took part in the study and their families
- The multi-disciplinary team of >1,200 investigators, study co-ordinators, nurses and staff who participated in the SIRFLOX study
- Sirtex Medical Limited, the study sponsor

# SIRFLOX Study Presentation




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# Synopsis of Discussant Review

- **Discussant: Professor Ricky Sharma – University of Oxford, UK**
  - Role of Discussant following the oral presentations (n=3) was to comprehensively and critically review study data via a 12-minute themed discussion

- **The Discussant comments relating to the SIRFLOX study were**
  - " Because of that burden of extra-hepatic disease we are not seeing a signal in PFS " – *refers to the primary endpoint of overall Progression-Free Survival (PFS)*
  - " There is an impressive change in local control in the liver "
  - " Reassured that these points fall where there are multiple events occurring; so this is a robust result " – *refers to the competing risk analysis of PFS in the liver*
  - " SIRT does have the capacity to improve local control in combination with FOLFOX chemotherapy but with slightly higher toxicity "
  - " Eagerly anticipate the sub-group analyses and the combined analyses which will tell us which patients benefit most from SIRT "
  - " For local control of liver metastases, SIRT is to have a role in combination with FOLFOX chemotherapy "



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# Synopsis of Expert Panel Discussion

- **Expert Panel Q&A**
  - Following the Discussant, a 12-minute Expert Panel Discussion and audience Question & Answer session was held to further critically review the study data
- **The highlights of the Expert Panel Discussion and Q&A relating to the SIRFLOX study were**
  - Several discussion points relating to various sub-groups of the SIRFLOX study, which have yet to be analysed and reported, included:
    - Re-section rates of the primary tumour and impact on survival
    - The site and time to progression of extra-hepatic metastases
    - KRAS status
  - On late stage toxicity, only one case was observed, at around the 30 month mark with no other evidence of late radiation effects
  - On discussion relating to Overall Survival (OS)
    - A/Prof. Gibbs does expect to see an OS benefit
    - OS data will also be important with respect to clinical practice



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# Key Opinion Leader Feedback

- **Key Opinion Leader (KOL) feedback on the SIRFLOX study is a critical component of the ASCO process and peer review**
  - **Builds** awareness of the results
  - **Educates** the medical community on its meaning
  - **Supports** future clinical adoption
  - Sirtex sought their view on the SIRFLOX results

# Key Opinion Leader Feedback

**Comments on the use of SIR-Spheres microspheres in clinical practice**

- **Professor Eric Van Cutsem, MD, PhD – University of Leuven, Belgium**

European Organisation for Research and Treatment of Cancer (EORTC) board member

*" The effect of Y-90 resin microspheres on Progression-Free Survival in the liver, as reported in the SIRFLOX study, is extremely encouraging. Although the primary endpoint of PFS at any site was not achieved, the 7.9 month improvement in liver PFS with SIR-Spheres Y-90 resin microspheres demonstrates the strength of this liver-directed therapy. The outcome of SIRFLOX suggests that oncologists who treat mCRC may now consider earlier use of Y-90 resin microspheres in combination with systemic chemotherapy in liver limited disease. "*

*" The SIRFLOX study results provide robust Level 1 evidence for medical oncologists to incorporate in their daily clinical practice. "*

# Key Opinion Leader Feedback

## Comments on the use of SIR-Spheres microspheres in clinical practice

- **Dr Harpreet Wasan, MD, PhD – Imperial College Trust, London, UK**

European Working Party on CRC Liver Metastases Guidance

*" Oncologists are only now beginning to recognise that treating liver metastases directly by integrating local approaches, as well as systemically (with cancer drugs) is more effective in the management of this difficult-to-treat cancer, and may also open up the possibility of potentially curative liver surgery in some previously inoperable cases. "*

*" The results of this study show that the effect of SIR-Spheres on slowing the growth of liver cancer tumours, within the liver is quite pronounced – The addition of SIR-Spheres adds eight additional months of control within the liver, that is without the tumours progressing in the liver. Compared to systemic chemotherapy this is a considerable amount in cancer therapy terms, particularly in advanced liver cancer which takes so many lives. This is the first significant trial to show the effectiveness of SIR-Spheres used early (in first line use) alongside the current standard of chemotherapy care. In time, if this is reflected in clinical practice we may be able to stall the disease for much longer in a vital organ at an earlier stage of disease than we do currently with chemotherapy alone. We hope that this gain also translates into an overall survival benefit as tumours are treated more aggressively, earlier on in the course of the disease. "*



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# Key Opinion Leader Feedback

**Comments on the use of SIR-Spheres microspheres in the mCRC treatment paradigm**

- **Professor Volker Heinemann, MD, PhD – University of Munich, Germany**

Principal European Investigator, SIRFLOX Study

*“ Even in the absence of sufficient data to calculate an overall survival benefit or a significant finding for Progression-Free Survival outside of the liver, the outcome of SIRFLOX suggests that oncologists who treat mCRC may now wish to consider earlier use of Y-90 resin microspheres than is presently the case, certainly among those patients whose metastatic disease has been diagnosed primarily in the liver. ”*



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# Key Opinion Leader Feedback

**Comments on the safety and toxicity associated with the SIRFLOX study**

- **Assistant Professor Navesh K. Sharma DO, PhD – University of Maryland Medical Center, USA**

Principal US Investigator, SIRFLOX Study

*" It is important to observe that in SIRFLOX, the clinical benefit that was observed came with an acceptable level of adverse events from adding Y-90 resin microspheres to first-line chemotherapy in mCRC. Oncologists, especially radiation oncologists, have traditionally been very cautious of irradiating large liver volumes because of the adverse effects associated with such treatments. SIRFLOX has shown us, in an unbiased manner, that not only can we deliver high doses of radiation to the liver safely with this approach, but we can do so using concurrent chemotherapy. Concurrent chemo-radiation has been one of the most effective ways to treat cancer in general, especially those of gastrointestinal origin. "*

# Key Opinion Leader Feedback

**Comments on the clinical relevance of SIRFLOX**

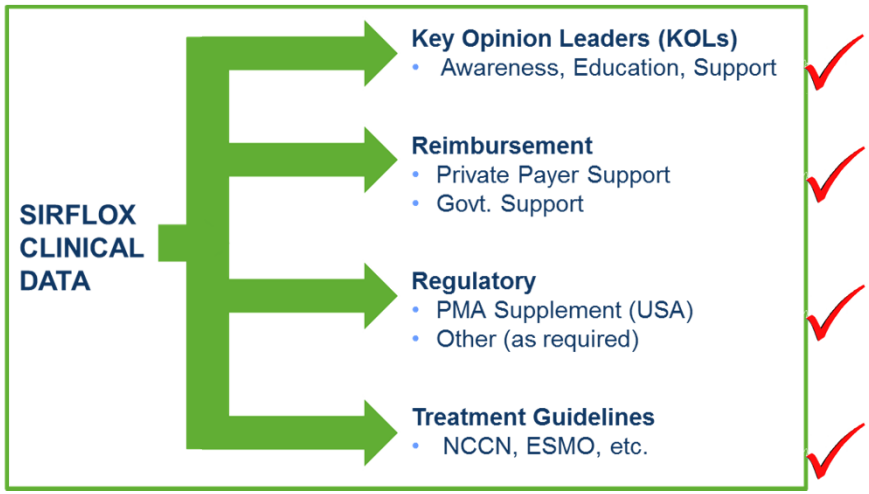
- **Professor Guy Van Hazel, MD – University of Western Australia**

Co-Principal Investigator on the SIRFLOX Study

*" SIRFLOX gives us the data to validate the clinical relevance of first-line use of selective internal radiation therapy, or SIRT, with SIR-Spheres Y-90 resin microspheres in mCRC. Until now, we have not had a randomized clinical study large enough to provide Level One evidence supporting first-line use of this treatment. "*

# Conclusions

- **SIRFLOX Study Peer Review at ASCO confirms**
  - Clinicians are enthusiastic about the result observed in the liver (median PFS benefit of 7.9 months, HR = 0.69, p = 0.002) with SIR-Spheres microspheres and the acceptable safety and toxicity
  - Result is highly significant and clinically meaningful in the liver
  - Peer review process now provides additional support for Sirtex strategies relating to KOLs, reimbursement, regulatory and treatment guidelines, which remain active
  - OS data eagerly anticipated, results expected in 2017 according to study investigators



# Outlook

- **The SIRFLOX Peer Review process is ongoing**
  - Results to be published in a leading peer-reviewed scientific journal, anticipated during the 2H of CY15
  - Additional study data to be presented at future medical conferences
- **As a result of the ASCO Peer Review process, Sirtex anticipates increased utilisation of SIR-Spheres microspheres in the first-line setting for metastatic colorectal cancer**
  - Clinical adoption into first-line expected to gain momentum over time
  - Uniqueness of SIRFLOX study with a liver-directed therapy + chemotherapy means education of the results to the Medical Oncology community is ongoing
- **Continued growth in current 'salvage' business**
  - 22% dose sales growth in first ten months of FY15
  - Record dose sales in March and April

# Thank You

# Questions?