



# Interventional Oncology

23 September 2014



Imagine where we can go.

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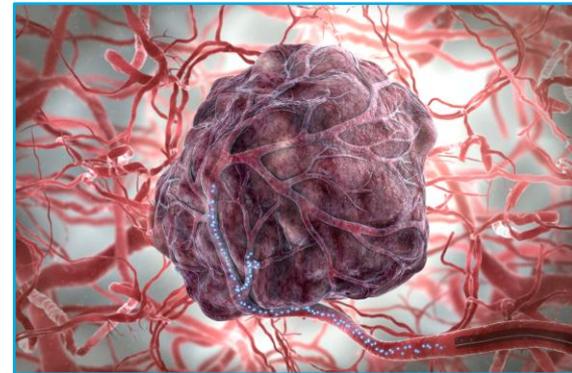
# Forward-looking statement



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# What is Interventional Oncology?

- Minimally invasive, image guided therapies which treat cancer locally at the tumour site
- Loco-Regional Therapy
- The “4th Pillar of Cancer Care”
- Patients may be referred by an Oncologist or Hepatologist to an Interventional Radiologist who specialises in Cancer
  - ***Interventional Oncologist***



# Interventional Oncology: the 4th Pillar of Liver Cancer Care



**Systemic  
Chemotherapy**



*“poison it”*



**External Beam  
Radiation**



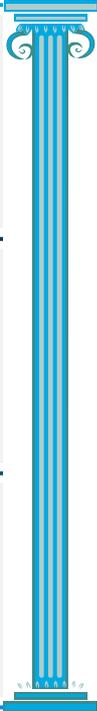
*“irradiate it”*



**Conventional  
Surgery**



*“remove it”*



## Loco-regional Therapies

TACE with Drug-  
Eluting Beads,  
e.g. **DC Bead®**

Radio-  
embolisation, e.g.  
**TheraSphere®**

Ablation, e.g. RF,  
Microwave

# Liver Cancers



## Primary liver cancer

- Primary liver cancer is a cancer that starts in the liver
- The two main types are:
  - Hepatocellular carcinoma (HCC) accounting for 85-90% of primary liver cancer – accompanied by underlying cirrhosis which complicates treatment
  - Biliary tree cancer, which includes cholangiocarcinoma (bile duct cancer), accounting for 10-15% of primary

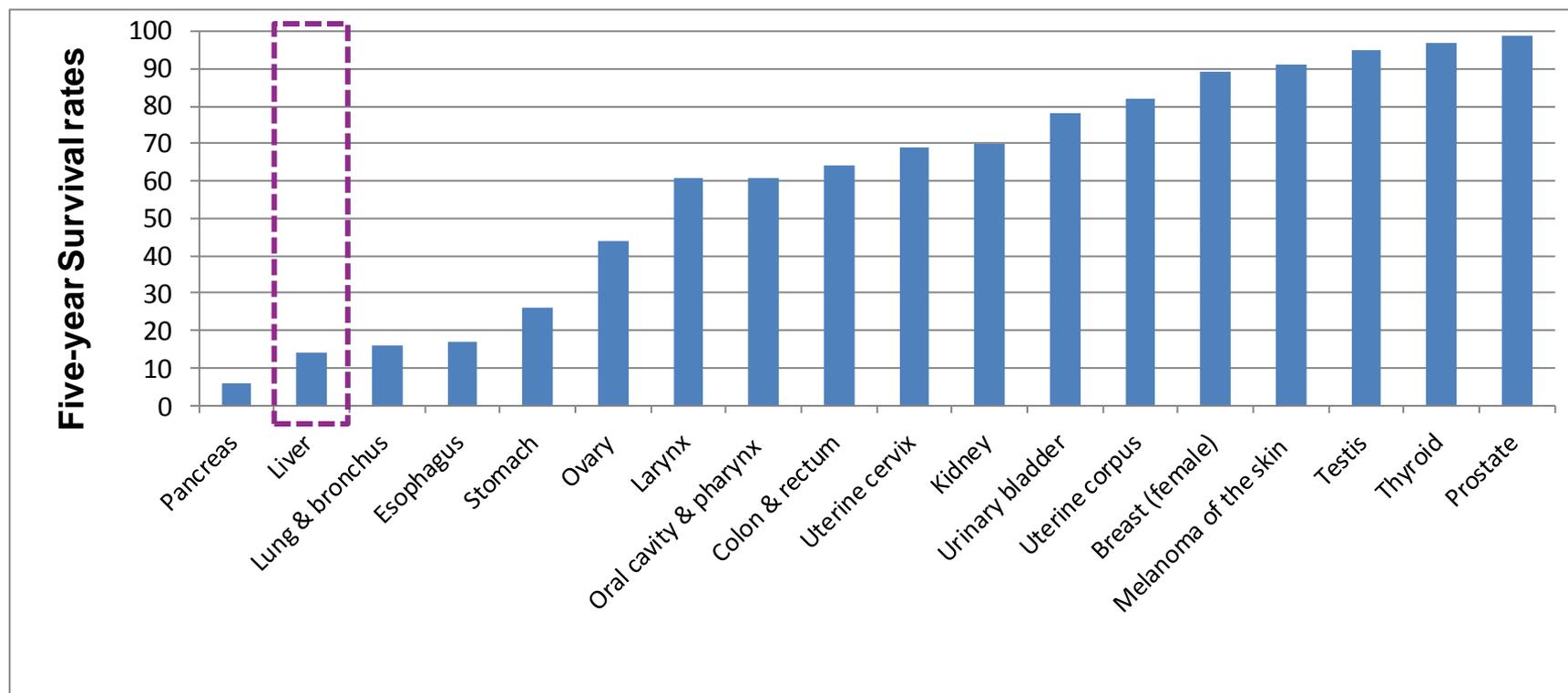
## Secondary liver cancer

- Secondary cancer first develops elsewhere in the body and then spreads (metastasizes) to remote organs, frequently the liver as it acts as a filter
  - Colorectal Cancer (mCRC)
  - Neuroendocrine Tumours (NETS), e.g. Pancreatic
  - Melanoma (Skin or Ocular)

# Liver cancer is one of the most fatal cancers



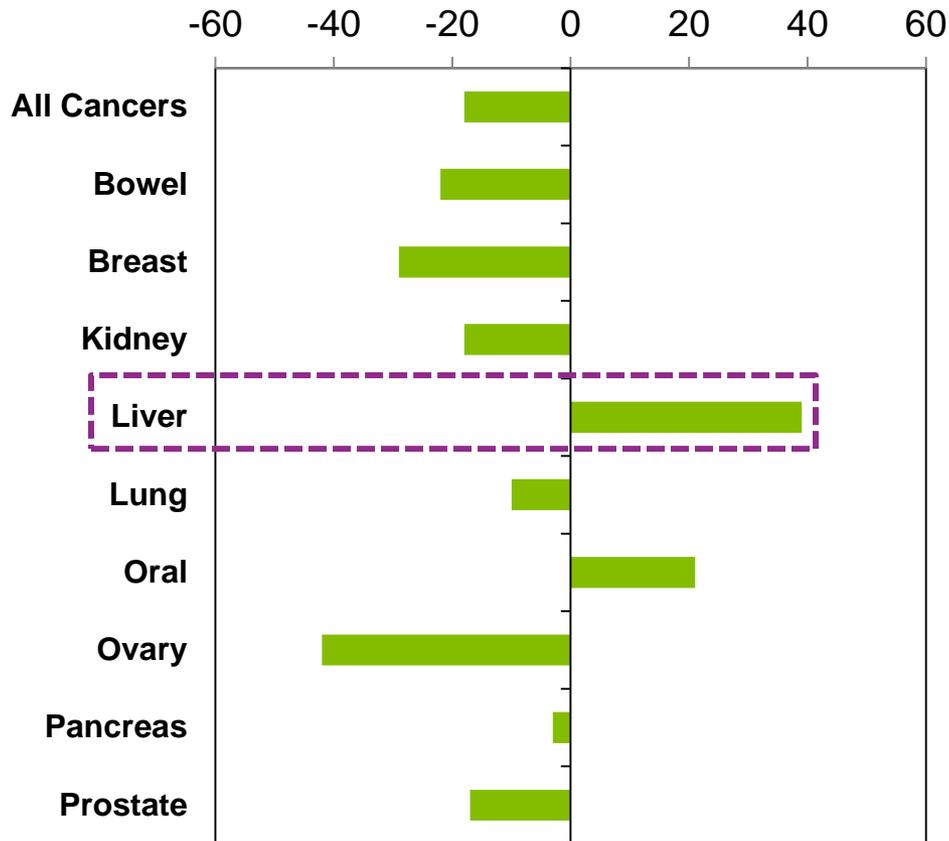
After pancreatic cancer, liver cancer is the deadliest cancer with the second lowest five year survival rates of only 14%<sup>1</sup>



<sup>1</sup> Cancer Facts & Figures 2012, American Cancer Society - US report

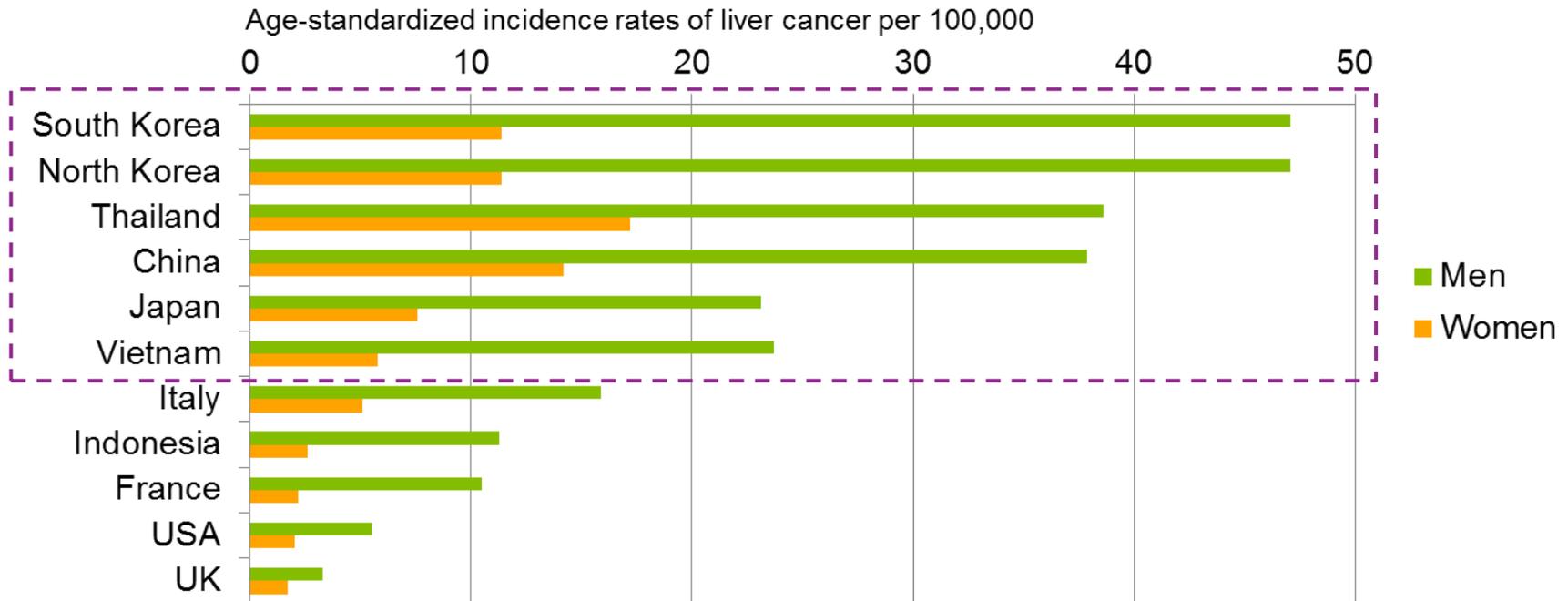
# Liver cancer is set to rise

Projected Cancer Mortality Rates, 2010 – 2030<sup>1</sup>



- Mortality rate for all cancers will fall by 17%
- Liver cancer mortality is predicted to increase by 39%
- The main reasons for growth in liver cancer are:
  - Growing population
  - Ineffective current treatments

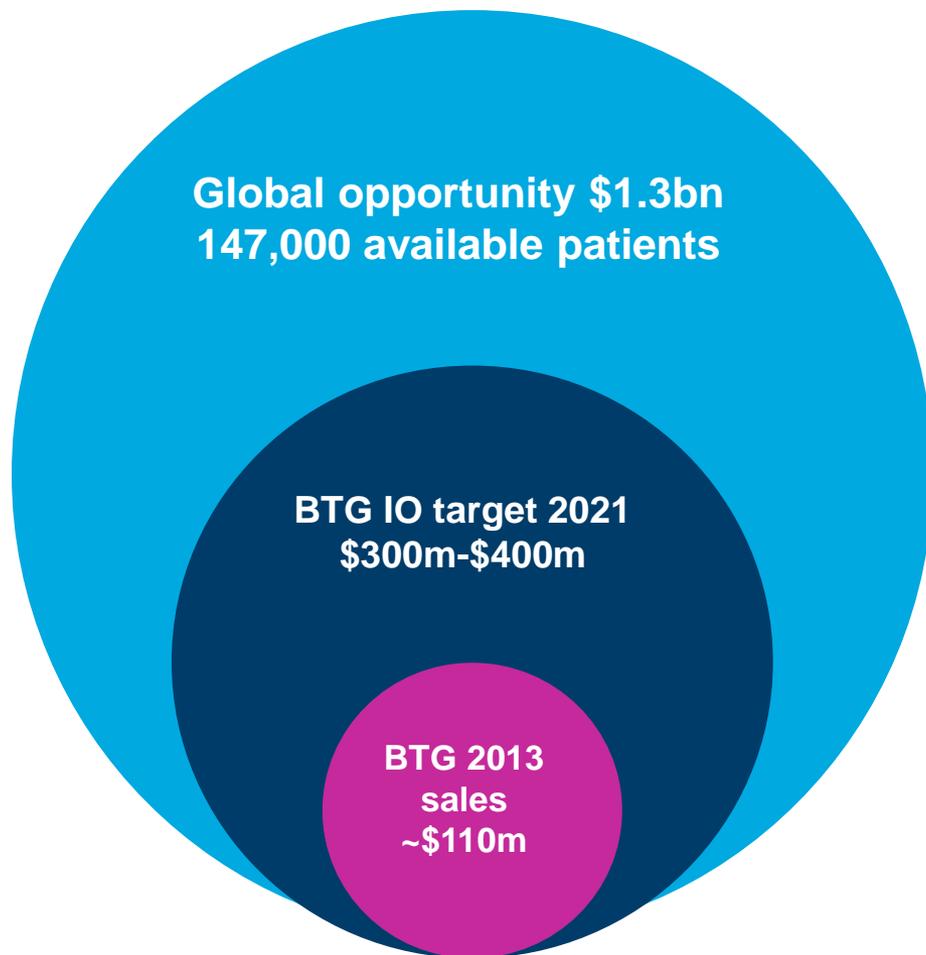
# Asia has the highest incidence of liver cancer overall



- Asia has the highest incidence of liver cancer per head of population in the world, accounting for nearly 50% of the world's total HCC population<sup>1</sup>
- Main risk factors include:
  - Infection via Hepatitis B and Hepatitis C Virus
  - Lifestyle (e.g. alcohol, obesity and smoking)

<sup>1</sup> Graph adapted from El-Serag HB, *Epidemiology of Viral Hepatitis and Hepatocellular Carcinoma Gastroenterology*, Vol143, Issue 1, July 2012, Page 269

# Significant global opportunity

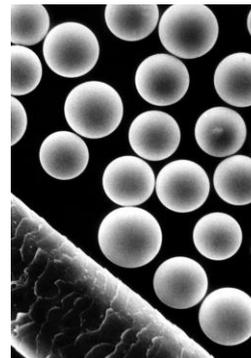


	Global market opportunity		
			
HCC	\$140m	\$140m	\$120m
mCRC	\$420m	\$400m	\$55m
Combined	\$560m	\$540m	\$175m
Total opportunity	\$1.3bn		

# What is TheraSphere®?



- Insoluble radioactive glass microspheres for the treatment of liver tumors
- Microspheres deliver a high-dose of radiation using yttrium-90 (Y-90) via the hepatic artery into the tumor
- Y90 is an integral component of the glass with a half life of 64.1 hours
- Microspheres are trapped in the tumor capillaries where they emit beta radiation
- The glass microspheres have a mean diameter of 20-30  $\mu\text{m}$
- Very high concentration of radioactivity per sphere (50x greater than competitor)



Y-90 glass microspheres  
comparison to human hair  
(8  $\mu\text{m}$  diameter)

# TheraSphere<sup>®</sup> Phase III Clinical Studies



Trial name	Trial description	Number of patients	Trial design	End-points
<b>STOP HCC</b> Advanced HCC PMA	Patients randomised (1:1) to TheraSphere <sup>®</sup> followed by sorafenib vs. sorafenib	390	<ul style="list-style-type: none"> <li>– Open label</li> <li>– Prospective</li> <li>– Randomised</li> <li>– Multi-centre, up to 100 sites in N. America, EU and Asia</li> </ul>	<ul style="list-style-type: none"> <li>– Primary: OS</li> <li>– Secondary: TTP, TTUP, TTSP, Tumor Response, QoL, Safety</li> </ul>
<b>YES-P</b> Advanced HCC with PVT	Patients randomised (1:1) to TheraSphere <sup>®</sup> vs. sorafenib	328	<ul style="list-style-type: none"> <li>– Open label</li> <li>– Prospective</li> <li>– Randomised</li> <li>– Multi-centre, ~25 sites in N. America, EU, Asia</li> </ul>	<ul style="list-style-type: none"> <li>– Primary: OS</li> <li>– Secondary: TTP, Time to worsening of PVT, TTSP, Tumor response, PRO, Safety</li> </ul>
<b>EPOCH</b> mCRC 2 <sup>nd</sup> line PMA	Patients randomised (1:1) to TheraSphere <sup>®</sup> + 2nd line chemo vs. 2nd line chemo	340	<ul style="list-style-type: none"> <li>– Open label</li> <li>– Prospective</li> <li>– Randomised</li> <li>– Multi-centre, up to 100 sites in US, Canada, EU, Asia</li> </ul>	<ul style="list-style-type: none"> <li>– Primary: PFS</li> <li>– Secondary: OS, HPFS, TTSP, Disease Control Rate, QoL, Safety</li> </ul>

# What Are Drug-Eluting Beads?

[https://www.youtube.com/watch?v=PkJcVuI\\_J74](https://www.youtube.com/watch?v=PkJcVuI_J74)



Manufactured in  
Farnham UK and  
Frankfurt, Germany

# DC Bead<sup>®</sup>

## A Unique Drug Delivery Embolisation System



- **CE marked** primarily for embolisation of malignant hypervascular tumours
- Capable of uniform **loading** and **controlled local and sustained elution** of doxorubicin or irinotecan as a secondary action
- Available in a range of calibrated sizes:
  - 70-150 $\mu$ m (DC BeadM1<sup>™</sup>)
  - 100-300 $\mu$ m
  - 300-500 $\mu$ m
  - 500-700 $\mu$ m
- Loaded at point of use (usually in the pharmacy)
- Designed for optimum delivery via a microcatheter, no aggregation, ease of handling, durable suspension





BTG

# Innovation

## Beads Pipeline Projects

### Radiopaque Bead

- Real Time Display of embolic and/or drug delivery for Interventional Radiologist

### Biodegradable Bead

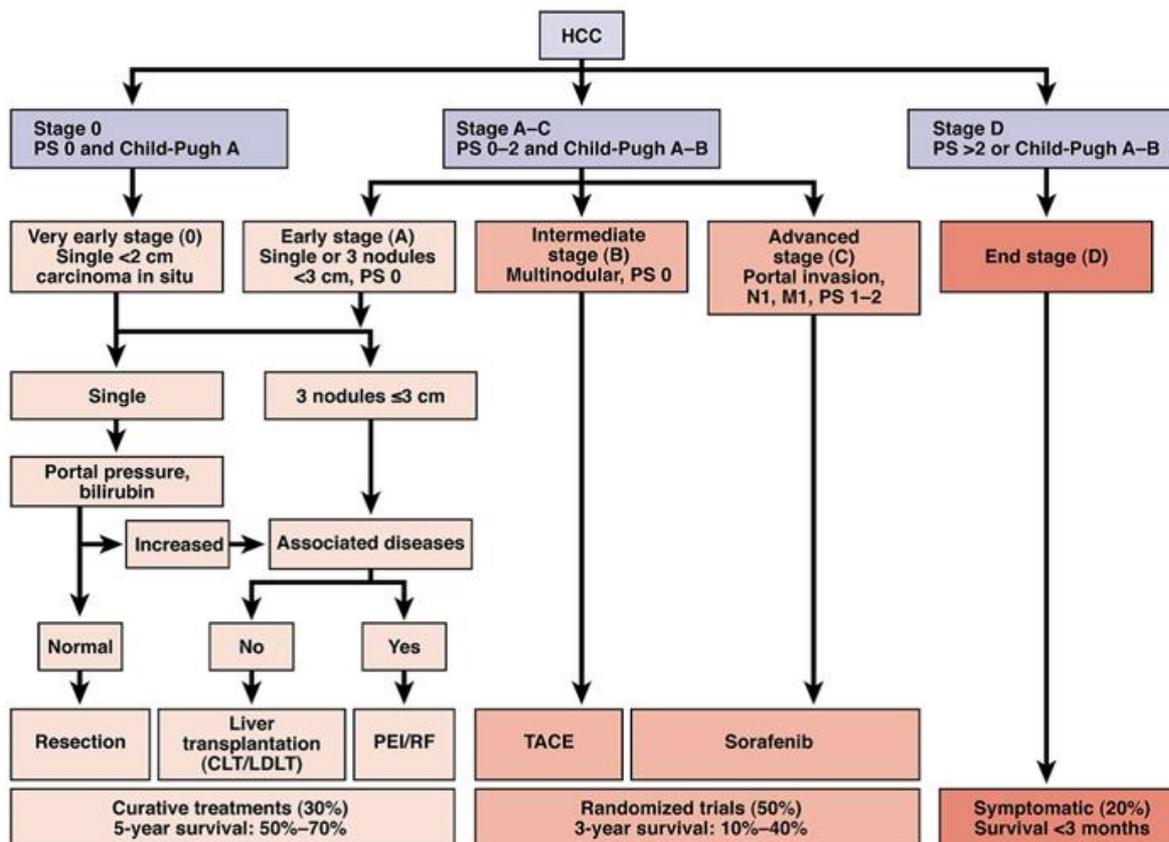
- For use in Non-liver Embolisation, e.g. uterine fibroids and benign prostatic hypertrophy

### Proprietary Drug Loaded DC Bead

- Improved anti-tumour effect using Beads to deliver targeted chemotherapy agents

# Where do our Products Fit?

## HCC BCLC Staging System



successful trials **DC BEADS** **THERASPHERE®**

^ Tumor size not absolute (BCLC B relates to tumors <8 cm. Literature supports use of TS in patients with larger tumors e.g., 9-25cm)

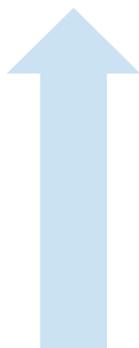
†Poor TACE candidates (BCLC A/B with >5 nodules, large tumors, lobar/bi-lobar disease, the elderly and BCLC C with partial PVT).

\*FDA/CMS definition is ≥65 but physicians may categorize them differently

# BTG Interventional Oncology Plan

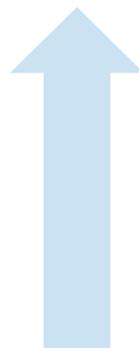


Potential \$300m - \$400m business by 2021



## Indication expansion

- Reinforce complementary market positions for Beads and TheraSphere®
- Deliver optimised, combined R&D programme of Beads and TheraSphere®



## Geographic expansion

- Capitalise on enlarged US sales force
- Expand EU footprint
- Maximise the Asian opportunity



## Innovation

- Enhance portfolio through product innovation and lifecycle management
- Radiopaque Bead, biodegradable Bead