

ASX Announcement 30 August 2018

# **OncoSil appoints IQVIA as EU Market Access and Reimbursement Advisor**

Sydney, Australia, 30 August 2018: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical or the Company) a medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to announce the appointment of IQVIA (NYSE: IQV) as its Market Access and Reimbursement advisor for the OncoSil<sup>™</sup> device in EU markets including France, UK, Germany and the Nordic countries.

# **Key highlights**

- Appointment of IQVIA as EU Market Access and Reimbursement Advisor represents a significant milestone for the Company commercialisation strategy
- IQVIA will work in collaboration with the Company to develop a strategic and effective approach to commercialisation of the OncoSil<sup>™</sup> device in key EU Markets
- IQVIA is a globally recognised leader in the provision of information, technology solutions and contract research services in the healthcare sector and brings deep experience commercialising breakthrough technologies

# Appointment of IQVIA accelerates path to early commercialisation of OncoSil device

OncoSil Medical is pleased to be working with IQVIA to ensure a successful transition to early commercialisation of the OncoSil<sup>™</sup> device across multiple European markets. IQVIA is a globally recognised leader in its field and was recently named in the Healthcare category of FORTUNE's 2018 list of "World's Most Admired Companies".

IQVIA will work with the Company to undertake detailed feasibility assessments, pathway specifications, and market penetration activities in the lead up to OncoSil Medical receiving CE Mark Certification and first commercial use of the OncoSil<sup>™</sup> device in patients.

IQVIA's appointment builds on considerable work already undertaken to date by the Company, and will be focused on evaluating a number of key areas critical to successful commercialisation including:

- Early and special reimbursement options;
- Private paying alternatives for patients
- Special funding for treatment of challenging cancers; and
- Reimbursement options at local, regional and national or governmental level.

Daniel Kenny, Chief Executive Officer of OncoSil Medical commented:

"We are pleased to be working with IQVIA as our Market Access and Reimbursement advisors for OncoSil across key markets in Europe. This appointment represents a significant milestone in the Company's commercialisation strategy in anticipation of securing CE Mark approval and moving into early commercialisation of our device over the coming months. We are excited to collaborate with IQVIA to develop an effective approach in each market as we near EU regulatory approval."



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### About OncoSil

OncoSil<sup>™</sup> is a clinical-stage medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil<sup>™</sup> is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil<sup>™</sup> is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical trials with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil<sup>™</sup> in the European Union (EU) is under review with commercial launch planned subject to approval.

The U.S Food and Drug Administration granted an Investigational Device Exemption (IDE) in July 2016 with approval to conduct a clinical study of the OncoSil<sup>™</sup> device. The aim of the study will be to collect safety and effectiveness data required to support a Premarket Approval (PMA) application.

Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil<sup>™</sup> in pancreatic cancer exceeds \$1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6<sup>th</sup> most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.

### About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions, and contract research services to the life sciences industry. Formed through the merger of IMS Health and Quintiles, IQVIA applies human data science — leveraging the analytic rigor and clarity of data science to the ever-expanding scope of human science — to enable companies to reimagine and develop new approaches to clinical development and commercialization, speed innovation, and accelerate improvements in healthcare outcomes. IQVIA has approximately 55,000 employees in more than 100 countries, all committed to making the potential of human data science a reality. IQVIA's approach to human data science is powered by the IQVIA CORE™, driving unique actionable insights at the intersection of big data, transformative technology and analytics with extensive domain expertise.

IQVIA is a global leader in protecting individual patient privacy. The company uses a wide variety of privacy-enhancing technologies and safeguards to protect individual privacy while generating and analyzing the information that helps their customers drive human health outcomes forward. IQVIA's insights and execution capabilities help biotech, medical device, and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders tap into a deeper understanding of diseases, human behaviors and scientific advances, in an effort to advance their path toward cures. To learn more, visit <u>www.IQVIA.com</u>.

### **Forward Looking Statements**

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing



approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.