



ASX / Media Release  
18 August 2016

## Supply Chain Validation and Hot Calibration Run of OncoSil™

**Sydney, Australia, 18 August 2016:** OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**), a late stage medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to announce that it has successfully completed a supply chain validation process including the first hot (radioactive) calibration delivery of OncoSil™.

In preparation for the commencement of the Company's planned global clinical study of OncoSil™ for the treatment of pancreatic cancer (**OncoPac-1**) and the commercialisation of OncoSil™ subject to attainment of CE Mark, the Company restarted de-novo manufacturing of OncoSil™ microparticles in January 2016. The manufacturing, supply chain validation and delivery to clinical and commercial centres of the OncoSil™ product is a key step to commercial sales and the treatment of patients in the OncoPac-1 Study.

In order to validate the manufacturing and distribution processes, the Company performed a full hot calibration run of OncoSil™ microparticles on Wednesday, 17 August 2016 in the Department of Nuclear Medicine, Royal North Shore (RNS) Hospital, Sydney which included initial training and calibration of their equipment to ensure dose accuracy of OncoSil™ microparticles in diluent suitable for a patient treatment.

The hot calibration run encompassed the full manufacturing of OncoSil™ microparticles including microparticle irradiation, packaging, shipping and delivery to the hospital. The successful completion of the hot calibration run verifies the functionality of the manufacturing and distribution processes.

OncoSil Head of Manufacturing, David James commented:

*"We are delighted with the safe and successful validation shipment of the dose to a typical clinical site as it demonstrates that we are prepared for the commencement of OncoPac-1 and commercialisation. It further shows that the staff, procedures, and commercial partners that the Company have assembled are accomplished at manufacturing and distributing the OncoSil product."*

- ENDS -

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## About OncoSil™

OncoSil is a clinical-stage medical device company seeking to provide a new medical radiation treatment for cancer patients. OncoSil's lead product, OncoSil™ is comprised of silicon-phosphorous-32 (p32) beta emitting microparticles which are implanted by endoscopy into localised solid tumours of patients with pancreatic cancer. Treatment with the OncoSil™ device, known as brachytherapy, is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil has conducted four clinical trials with encouraging results on tolerability, safety and efficacy. A CE Mark application for regulatory approval to commercially sell the OncoSil™ device in the EU and other non-US markets is under review with commercial launch planned for 2H2016, subject to approval. An Investigational Device Exemption has been granted by the United States Food and Drug Administration to conduct a clinical trial of the OncoSil™ device aimed at supporting an FDA approval. 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™ in pancreatic cancer exceeds \$1b.

## 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.