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ASIA EDITION

Australia's OncoSil Medical secures US FDA approval for cancer radiation device

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For the treatment of distal cholangiocarcinoma (dCCA) in the US



Australia-based OncoSil Medical, a medical device company developing targeted radiation therapies for difficult-to-treat cancers, has announced that the US Food and Drug Administration (FDA) has granted Humanitarian Device Exemption (HDE) approval for the OncoSil device for the treatment of distal cholangiocarcinoma (dCCA) in the United States.

The approval represents a significant milestone for OncoSil Medical, completing the company's HDE regulatory process and providing US marketing authorisation for OncoSil for this indication under the HDE framework.

US FDA approval represents a transformational step in OncoSil Medical’s US expansion, significantly broadening the commercial opportunity for the OncoSil platform and providing entry into the world’s largest healthcare market.

Approximately 8,000 people diagnosed with cholangiocarcinoma in the United States each year. dCCA is an anatomical subtype of cholangiocarcinoma and is estimated to account for approximately 30-40% of cholangiocarcinoma cases. Within the dCCA population, a subset of patients will fall within the population covered by the FDA-approved indication for OncoSil, which is limited to patients with dCCA that is both unresectable (locally advanced and/or unfit for surgery) and non-metastatic, as an adjunct to systemic therapy.

This represents an estimated patient pool of approximately 1,000 per annum and A$80 million annual Total Addressable Market (TAM) for the OncoSil device in the United States.