Oncosil wins CE mark, breakthrough designation for pancreatic cancer device

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April 1, 2020

PERTH, Australia – The British Standards Institute (BSI) granted Sydney-based Oncosil Medical Ltd. (https://www.cortellis.com/intelligence/qsearch/"Oncosil Medical") European CE marking approval for its brachytherapy device to treat locally advanced pancreatic cancer in combination with chemotherapy, clearing the way for marketing in both the EU and the U.K.

BSI also granted the Oncosil device breakthrough therapy designation. In March, the U.S. FDA granted breakthrough device designation to the device for treating unresectable pancreatic cancer.

The device delivers radiation directly to tumors in patients who have inoperable pancreatic cancer. The device emits radioactive beta particles that enter the tumor and damage cancer cell DNA, stopping cancer cells from multiplying and ultimately shrinking the tumor when the cells die.

“We have shown a prolonged median overall survival of 16.1 months in an unresectable locally advanced pancreatic group, and the median overall survival of that group is roughly eight months, so we effectively doubled overall survival,” Oncosil CEO Daniel Kenny told BioWorld.

“The breakthrough therapy designation is granted based on the FDA criteria, which is all about unique technology providing a benefit that’s not seen with therapies on the market. But the driver behind that is prolonged overall survival and the ability to downstage unresectable advanced pancreatic cancer status to resectable.
“In the Panco study we’re showing a resection rate of just under 24%, and in unresectable pancreatic cancer, that’s a great outcome.”

For patients who present as unresectable, or inoperable, their outcomes are “very poor,” but if you can downstage the tumor, you can “radically change the outcome,” and that could extend their lives by years, he said.

In addition to overall survival, the Panco study, which was run in multiple sites in Australia and Europe, showed prolonged progression-free survival of 9.3 months (p<0.001), marked tumor volume reduction (median volumetric reduction was 38% at 16 weeks), among other secondary outcome measures.

The active phase of the Panco study is completed, and will be followed by a two-year follow-up period, which is being extended beyond because half of the 42 implanted patients are still alive.

Oncosil is working closely with the U.S. FDA to ensure that the premarket approval (PMA) evidence and trial design captures the right information for the post-market setting, which is required for breakthrough devices.

“Breakthrough designation also provides validation of the Oncosil device as it represents a novel technology that has the potential to provide clinically meaningful benefits to patients in terms of increased overall survival and downstaging tumors to resection with curative intent,” Kenny said.

"Because it is a breakthrough therapy and a very unconventional way of delivering the therapy directly to the tumor, the FDA required a 20-patient safety run-in (articles/409564-australia-s-oncosil-brachytherapy-device-begins-pivotal-study-in-pancreatic-cancer) of the trial," Kenny said, noting that the agency was most concerned about the implant procedure rather than the radiation.

The device is comprised of phosphorous-32 microparticles and a diluent that acts as a carrier. The microparticles deliver a localized distribution of beta radiation within the target tumor that remain in the tumor following implantation. The radiation is delivered over 81 days.

Most patients get biopsies of their tumors, which provides additional information about tumors that might present more risk, such as highly vascular tumors.

"Their biggest concern is around the delivery of the device via ultrasound-guided endoscopy. And although we've treated 42 patients for pancreatic cancer, they’re worried about the endoscopies rupturing blood vessels or the risk of seeding going in and out of the tumor," he said.

"Once the device is implanted it stays in situ, and the healthy tissue around the tumor is not impacted by the radiation," Kenny said, noting that the company had numerous discussions with the FDA.

The FDA also granted the device a humanitarian use designation (HUD) for intrahepatic and distal cholangiocarcinoma. The FDA also told the company that the clinical data for the pancreatic indication could be used for a predicate approach for a humanitarian device exemption.

**COVID-19 delays launch**

Kenny said the COVID-19 pandemic will delay launch plans in Europe and the U.K. due to limited hospital capacity. He is looking forward to a launch in the fall.

"With the compelling data we’ve got, we will now file in ASEAN and APAC countries in pancreatic cancer, and we will complete our HUD filing in distal cholangiocarcinoma with the FDA, and these things are not impacted by COVID-19,” he said.
He anticipates filing in May for the HUD for distal cholangiocarcinoma, which is a 75-day procedure.

Kenny said Oncosil is in active discussions with the FDA about the pancreatic cancer indication. A larger trial will be required for the PMA under the breakthrough designation in the U.S.