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Aussie firm gets TGA approval for pancreatic cancer drug

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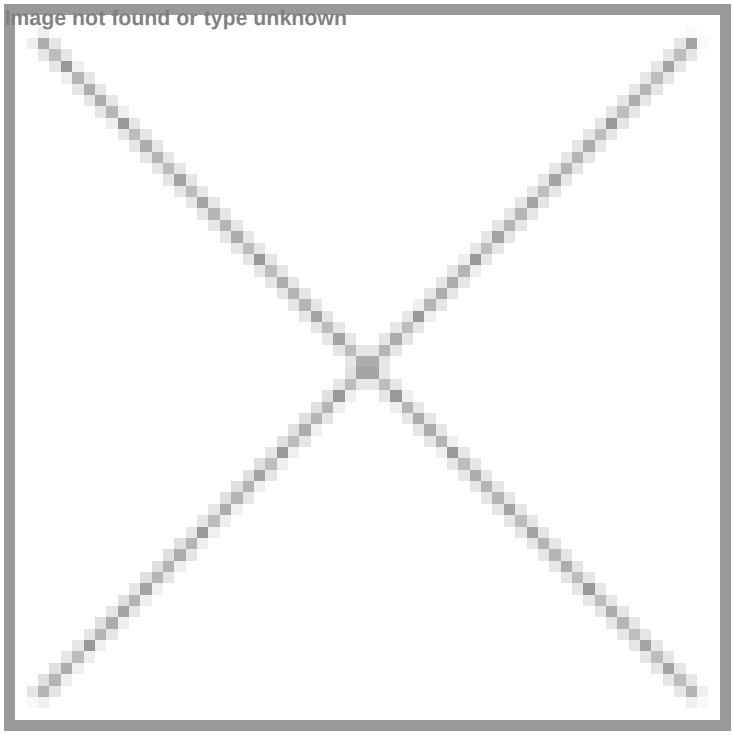

Singapore: Australian biopharmaceutical company, Specialised Therapeutics Australia (STA), has recieved Therapeutic Goods Administration (TGA) approval for ABRAXANE (nanoparticle albumin-bound paclitaxel) in combination with gemcitabine for the first-line treatment of metastatic pancreatic cancer.

TGA approval was based on the pivotal randomised phase III trial, MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial), published in the New England Journal of Medicine (NEJM) in October 2013.

MPACT is the first phase III trial in metastatic pancreatic cancer to report greater than 3-year survival rates, with 4 percent of patients in the ABRAXANE plus gemcitabine arm alive after three years, and 3percent of patients alive at 42 months, compared to 0 percent in the gemcitabine alone arm at both time points.

Mr. Carlo Montagner, CEO, STA, said, "TGA approval paves the way for Australian patients with metastatic pancreatic cancer to access this more effective treatment option. In Australia, pancreatic cancer is the fifth most common cause of death from cancer for both men and women, and very few treatment options exist for this group of patients. No new drugs have been approved by the TGA for this disease since 2006. We are extremely pleased to receive TGA approval in recognition that ABRAXANE is capable of prolonging survival for patients with metastatic pancreatic cancer, and look forward to a Pharmaceutical Benefits Scheme (PBS) listing for this difficult to treat cancer."

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