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ABRAXANE phase III trial shows improved results

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Singapore: A phase III clinical trial of world leading breast cancer drug ABRAXANE (nanoparticle albumin-bound paclitaxel) in combination with current standard of care gemcitabine by Australian biopharmaceutical company Specialised Therapeutics Australia in patients with advanced pancreatic cancer has demonstrated substantially improved survival times, with double the number of patients surviving two years.

The MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial) investigation involved 861 treatment naÃ¯ve patients internationally.

Researchers found those patients treated with ABRAXANE plus gemcitabine had a statistically significant improvement in overall survival compared to patients receiving gemcitabine alone [(median of 8.5 vs. 6.7 months) (HR 0.72, P=0.000015)].

Moreover, ABRAXANE plus gemcitabine demonstrated a 59% increase in one-year survival (35 percent vs 22 percent, p=0.0002) and demonstrated double the rate of survival at two years (9 percent vs. 4 percent, p=0.02) as compared to gemcitabine alone.1

ABRAXANE plus gemcitabine also demonstrated statistically significant improvements in key secondary endpoints compared to gemcitabine alone, including a 31 percent reduction in the risk of progression or death with a median progression-free survival (PFS) of 5.5 vs. 3.7 months (HR 0.69, P=0.000024) and an overall response rate (ORR) of 23 percent compared to 7 percent (response rate ratio of 3.19, p=1.1 x 10-10). Another endpoint assessed included time to treatment failure, which was significantly improved with the ABRAXANE combination compared to gemcitabine alone [(median 5.1 vs. 3.6 months) (HR 0.70, P < 0.0001)].

"The past few decades have brought us very few treatment advances for patients with advanced pancreatic cancer, which is both deadly and incredibly difficult to treat with success," said Mr Daniel D Von Hoff, MD, FACP, lead principal investigator of the MPACT study and chief scientific officer for Scottsdale Healthcare's Virginia G Piper Cancer Centre Clinical Trials and

Physician-In-Chief for TGen. "The fact that ABRAXANE plus gemcitabine demonstrated an overall survival benefit, and also did so at one and two years, is a significant step forward in offering potential new hope for our patients."

Professor John Zalcberg, chief medical officer and executive director of Cancer Medicine at the Peter MacCallum Cancer Centre in Melbourne, said the evidence strongly supported using ABRAXANE in combination with gemcitabine as a new standard of care to treat appropriate patients, many of whom were not diagnosed until the disease was metastatic.
While acknowledging that this advance could not be seen as a cure for pancreatic cancer, Professor Zalcberg said the 59 percent increase in the number of patients who lived beyond 12 months was very encouraging.

"We are extremely encouraged by the results of this study involving ABRAXANE and regard this outcome as a significant breakthrough in terms of the future management of this disease," he said. "In addition to treating women with metastatic breast cancer with ABRAXANE in the appropriate setting, we look forward to its approval in Australia for treating patients with advanced pancreatic cancer."

Specialised Therapeutics Australia (STA) Chief Executive Officer Mr Carlo Montagner said the positive data paved the way for Australian patients with advanced pancreatic cancer to access more effective treatment options.
He commented: "In Australia, pancreatic cancer is the fourth most common cause of death from cancer for both men and women and very few treatment options exist for this group of patients. We are extremely pleased to demonstrate that ABRAXANE is capable of prolonging survival for patients with advanced pancreatic cancer and we hope to have ABRAXANE approved by the Australian Therapeutic Goods Administration (TGA) in the latter half of 2014."

The most common grade â‰¥ 3 treatment-related adverse events in the study for ABRAXANE plus gemcitabine vs. gemcitabine alone were neutropenia (38 percent vs. 27 percent), fatigue (17 percent vs. 7 percent), and neuropathy (17 percent vs. 1 percent). In the ABRAXANE plus gemcitabine arm, the median time to neuropathy improvement was 29 days. There was no difference in serious life threatening toxicity (4 percent in each arm).