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ASIA EDITION

APAC Biotech gets approval for APCEDEN

April 6, 2017 | News | By BioSpectrum Bureau

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Singapore: Indian biotechnology company, APAC Biotech, is granted with a commercial license by Indian FDA (CDSCO - Central Drugs Standard Control Organization) to market product, APCEDEN, a Dendritic cell-based autologous Immuno-oncology product for four cancer indication namely Prostate, Ovarian, Colo-rectal and Non Small Cell Lung carcinoma.

The Indian Food and Drug Administration authorities after their stringent review of the application have issued the commercial license (Form 46) to conduct a post marketing surveillance on statistically significant number of patients for each indication.

Other products namely STEMPEUCEL, an allogeneic-cultured mesenchymal cells from Stempeutics and OSSORON, an autologous-cultured adult osteoblast and CHONDRON, an autologous-cultured adult chondrocyte from Regenerative Medical Services, Mumbai, also received the marketing license at the same time.

"The past decades have seen revolutionary progress in the development and application of cell and genetic engineering in an effort to personalize the treatment of cancer. We are now confident that it is possible to treat cancer patients using this approach as observed during clinical trials across India. The results are encouraging and mark a potential new paradigm in treating these solid tumors that do not respond to standard therapies," said a leading oncologist, Dr. Ashok Vaid.

APCEDEN, an autologous monocyte-derived mature Dendritic cell when loaded with tumor antigen have the ability to generate an effective immune response against the tumor. In the year 2011, an ATTEST trial was conducted where refractory solid tumor with multiple chemo failure patients were enrolled and administered with APCEDEN. The results were published in International Journal of Cytotherapy in the year 2014. ATTEST study included a stringent logistics management and was uniquely, effectively, conducted under the leadership of Principal investigator, Medical oncologist, Dr. P P Bapsy.