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Singapore: Australia biotech firm, Prescient Therapeutics, a clinical stage oncology company, has secured agreement from the United States Food and Drug Administration (FDA) to transfer the sponsorship to Prescient of the investigational new drug (IND) PTX-200, the company's lead product.

PTX-200, previously known as TCN-P (triciribine phosphate monohydrate), is a potent small molecule inhibitor of the AKT pathway, which plays a key role in the development of many cancers, including breast, ovarian cancer as well as hematologic cancers such as Acute Myeloid Leukemia.

PTX-200 is currently the subject of two pivotal trials in breast and ovarian cancer underway at prestigious US Cancer Centers. The first trial is a Phase 1b/2 trial in patients with platinum resistant ovarian cancer at the Moffitt Cancer Center, an NCI-designated cancer hospital in Tampa, Florida. The second trial is a Phase 1b/2 study in breast cancer patients at the Montefiore Medical Center, the academic medical center and University Hospital for Albert Einstein College of Medicine in Bronx, New York.

Dr Robert Crombie, managing director, Prescient Therapeutics, commented, "Clinical development in the US under an IND is a major regulatory pathway for gaining drug approval. Prescient is one of a very small number of ASX-listed biotechnology companies conducting clinical studies under an IND in the US. We look forward to advancing the clinical development of this drug candidate as a new therapy to treat cancers, which have become resistant to front line chemotherapies. Preclinical and clinical data amassed to date indicates this candidate has great potential as a new therapy to help break this resistance."