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Teikoku Pharma gets USFDA nod for non-alcohol docetaxel injection

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Singapore: Japan's Teikoku Pharma has recieved USFDA approval for Docetaxel injection, a non-alcohol formula for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

Teikoku entered into an exclusive licensing agreement with Eagle Pharmaceuticals in October 2015 to market, sell and distribute Docetaxel Injection in the US.

The main difference, compared to other docetaxel formulations, is that Docetaxel Injection is the first non-alcohol formulation approved in the US.

The need for non-alcohol docetaxel gained visibility in June 2014 when the FDA issued a Drug Safety Communication warning patients that docetaxel may cause symptoms of alcohol intoxication after treatment. Manufacturers of docetaxel formulations for domestic use were subsequently required to revise their product labels to warn about this risk. Some US hospitals and clinics require patients to wait two or more hours after treatment with docetaxel before they can be released.

"Docetaxel Injection addresses a compelling need in the docetaxel market. As the first alcohol-free formulation approved in the US, we believe the benefits of this novel formulation will provide an option for patients with alcohol sensitivity or a preference for an alcohol-free treatment. We are excited to add alcohol-free docetaxel to our growing portfolio of differentiated injectable products and believe it has the potential to improve the lives of patients, resolve concerns among health care

professionals at hospitals and infusion centers, and ultimately drive value for Eagle stakeholders," said Mr Scott Tarriff, president and chief executive officer, Eagle Pharmaceuticals.

"The approval of Docetaxel Injection, our first oncology product, is a significant milestone in Teikoku's history, and Docetaxel Injection marks our second FDA approved product as New Drug Application (NDA). In addition, Eagle Pharmaceuticals' strong presence in the oncology space makes Eagle an excellent partner for our product," said Mr Paul Mori, president and CEO of Teikoku.