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ASIA EDITION

Austrianova files Drug Master File with FDA for Cell-in-a-Box products from HEK293 cells

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Cell-in-a-Box® encapsulated cell products using encapsulated HEK293 cells and derivatives such as CypCaps™,the encapsulated cell product to use in their late-stage clinical trial for locally advanced, inoperable pancreatic cancer

S.E. Asian company, Austrianova, headquartered in Singapore, announced on 28 July 2020 that it has filed a Drug Master File (DMF) with the U.S. Food and Drug Administration (FDA). This DMF provides all confidential and detailed information covering the production of Cell-in-a-Box® encapsulated cell products using encapsulated HEK293 cells and derivatives such as CypCaps™, the encapsulated cell product that its' partner and client PharmaCyte Biotech Inc., is about to use in their late-stage clinical trial for locally advanced, inoperable pancreatic cancer.

Austrianova's CEO, Brian Salmons, said "The filing of this comprehensive DMF is an important milestone event for both Austrianova and PharmaCyte Biotech Inc., and represents a culmination of many years work on cell encapsulation based on this cell line. The DMF deposited with FDA describes confidential and detailed information about facilities, processes, and materials used in the manufacturing, processing, packaging, and storing of Cell-in-a-Box® products based on HEK293 cells. The information contained in the DMF will be used to support PharmaCyte's Investigational New Drug Application (IND) for CypCaps™ for the treatment of pancreatic cancer and thus the upcoming clinical trials."

A DMF is a document that is submitted to a regulatory agency and contains complete information on an Active Pharmaceutical Ingredient and/or finished Drug Product. It comprises factual and complete information on a Drug Product's raw materials, process development and manufacture, analytical methods, stability, purity, packaging and its cGMP status. The DMF filing allows a company to protect its' intellectual property from partners while complying with regulatory requirements for disclosure of processing details.