

EntreMed seeks SFDA nod for cancer trial

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Singapore: EntreMed, a clinical-stage pharmaceutical company developing therapeutics for the treatment of cancer, announced that EntreMed has submitted a new drug clinical trial application with China's State Food and Drug Administration (SFDA) for its proprietary drug candidate, ENMD-2076, to conduct global clinical trials in triple-negative breast cancer patients.

Dr Ken K Ren, EntreMed's chief executive officer, commented, "We are very pleased with SFDA's acceptance of our application package and look forward to working with the SFDA to move the process forward towards approval. SFDA's approval of our application would pave the way for us to conduct global clinical trials in China and advance our ongoing phase II triple-negative breast cancer trial currently underway at the University of Colorado and Indiana University.

"Our filing with SFDA represents an important milestone for us. As a clinical-stage drug development company, competition in patient recruitment, time, and costs can be challenging when advancing clinical programs. We address this by building a value-added platform via a joint US-China drug development model that will enable us to do the trials with lower study costs and faster patient recruitment. The data we obtain may be used to support both global drug development and China import drug registration as appropriate," said Dr Ren.

Dr Ren continued, "We will also pursue developing ENMD-2076 in other indications where activity has been shown, including ovarian cancer, sarcoma and liver cancer, based on our prioritized product development plan. We believe positive results from these efforts will add value to our patients, shareholders, as well as to the company.

"In addition, we have initiated local manufacturing and pre-clinical activities of ENMD-2076 in China to target specific unmet medical needs, such as hepatocellular carcinoma, which could support a new drug trial application with SFDA. Our local development activities demonstrate EntreMed's commitment to develop a strong presence in the Chinese market, which has been projected to become the second largest pharmaceutical market in coming years. We believe we are on track with our development plan and are grateful to our shareholders for their enthusiasm, patience, and long term support."