BioSpectrum the business of Bio & Health Sciences ASIA EDITION

SFJ Pharma, Pfizer collaborate for dacomitinib trial

10 September 2012 | News | By BioSpectrum Bureau

SFJ Pharma, Pfizer collaborate for pan-HER inhibitor dacomitinib trial

Singapore: SFJ Pharmaceuticals, primarily focused on funding and executing phase III studies of drugs, has entered into a collaborative development agreement with Pfizer to conduct a phase III clinical trial of Pfizer's investigational pan-HER (pan-human epidermal growth factor receptor) inhibitor dacomitinib (PF-00299804). The trial, which will be conducted across multiple sites in Asia and Europe, will evaluate dacomitinib as a first-line treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor (EGFR).

Under the terms of the agreement, SFJ will provide the funding and clinical development supervision to generate the clinical data necessary to support a registration dossier on dacomitinib for marketing authorization by regulatory authorities. The indication is first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR activating mutations. If approved for this indication, SFJ will be eligible to receive milestone payments and earn-out payments.

This is the second collaborative agreement between SFJ and Pfizer. SFJ previously entered into an agreement with Pfizer to conduct a phase III trial in Asia of Pfizer's Inlyta (axitinib) for the adjuvant treatment of patients at high risk of recurrent renal cell carcinoma following nephrectomy.

"At SFJ, our mission is to accelerate the availability of new and innovative drugs into the world's major markets through co-development," said Mr Robert DeBenedetto, president & CEO, SFJ. "With this important, multi-national trial, we are pleased to continue our collaborative relationship with Pfizer and support the clinical development of a promising new agent for the treatment of lung cancer."

"Pfizer is committed to building innovative partnerships that enable us to advance our clinical development programs and deliver new cancer medicines to patients as efficiently as possible around the world," said Mr Garry Nicholson, president and general manager, Pfizer Oncology. "Non-small cell lung cancer remains a difficult disease to treat despite recent advances, and Pfizer is evaluating dacomitinib in NSCLC across lines of therapy and a range of histologies and molecular subtypes. By collaborating with SFJ on the continued clinical development of dacomitinib in this patient population, we hope to more

immediately bring a new first-line therapy to patients in need."

Dacomitinib is an oral, once-daily, small molecule inhibitor of HER-1 (EGFR), HER-2 and HER-4 tyrosine kinases. It is being evaluated by Pfizer in a comprehensive clinical development program that includes two global, randomized phase III clinical trials investigating its safety and efficacy as a second-line and refractory treatment for NSCLC. Dacomitinib has not been approved by any regulatory agency.

Photo: Bigstock