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China NMPA Approves Sinovant's Clinical Trial Application for Lefamulin

14 June 2019 | News

Chinese registrational clinical trial for lefamulin to begin in 2H 2019

Sinovant Sciences announced on 13 June 2019, that its Clinical Trial Application (CTA) for lefamulin has been accepted by the Center for Drug Evaluation at the China National Medical Products Administration (NMPA), enabling the initiation of registrational clinical trials for patients with community-acquired bacterial pneumonia (CABP) in the second half of 2019.

"The approval of our CTA for lefamulin is a significant moment in the field of antibiotics in China," said Dr Rae Yuan, President of Sinovant. "High rates of resistance to existing antibiotics, particularly among the pathogens responsible for CABP, reduce the efficacy of historic first-line therapeutics and compromise millions of patients' chances of recovery. With its differentiated and novel mechanism of action, lefamulin has the potential to become a preferred first-line empiric monotherapy for CABP, and we are eager to deliver this important new medicine to Chinese patients."

Lefamulin is a novel semi-synthetic antibiotic of the pleuromutilin class being developed as a potential treatment for community-acquired bacterial pneumonia (CABP). CABP is one of the leading causes of mortality in China. Lefamulin works by selectively inhibiting translation of bacterial protein synthesis. In pre-clinical studies, lefamulin has demonstrated a targeted spectrum of activity against the pathogens that most commonly cause CABP, including multi-drug resistant strains. Due to its novel mechanism of action, low incidence of cross-resistance between other antibacterial agents commonly used to treat CABP, and low propensity for bacterial resistance to develop[1], lefamulin has the potential to be used as a first-line empiric monotherapy for the treatment of CABP. Sinovant's partner Nabriva has completed two global Phase 3 studies of lefamulin in patients with moderate and severe CABP. In both studies, lefamulin was demonstrated to be non-inferior to moxifloxacin, and met both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) primary and secondary efficacy endpoints for the treatment of CABP.

"This CTA approval is an exciting moment for us," said Dr Xinan Chen, Executive Chairman of Sinovant. "We are looking forward to embarking on the next chapter for Sinovant as we advance lefamulin into the clinic."