

Reistone Announces First Patient Dosed in Two Phase II Global Studies of SHR0302

17 June 2019 | News

Selective JAK1 inhibitor advanced into global Phase II trials for Ulcerative Colitis and Crohn's Disease in China



Reistone Biopharma Company Limited (Reistone), on 14 June 2019, announced dosing of the first patient in their Phase II global clinical trials (RSJ10101 and RSJ10201) of SHR0302 in patients with Ulcerative Colitis and Crohn's disease respectively. The Phase II studies are randomized, double-blind, placebo-controlled, four arms parallel, multi-centre Phase II study to investigate the safety and efficacy of SHR0302 in patients with moderate to severely active Ulcerative Colitis and Crohn's Disease.

Inflammatory Bowel Diseases (IBD) are a group of chronic progressive, inflammatory, autoimmune diseases affecting the gastrointestinal system. Ulcerative colitis (UC) and Crohn's disease (CD) are the two main types of IBD. It is estimated there are at least 2 million people suffering from Ulcerative Colitis, and one million people suffered from Crohn's disease globally. Despite recent advancement in treatment, there is still a significant unmet medical need in this area. In 2016, the global Ulcerative Colitis and Crohn's disease markets were estimated at about \$5 billion and \$10 billion US dollars respectively.

SHR0302 is a novel, potent, orally administered selective Janus kinase 1 (JAK1) inhibitor in development as a treatment for inflammatory bowel diseases. JAK1 selectivity could potentially provide a favourable safety and efficacy profile compared to the pan-JAK inhibitor.

"We are excited to advance our selective JAK1 inhibitor into our global Phase II trials for UC and CD. Reistone is committed to bringing this innovative drug developed in China to the world," said Dr Min Irwin, CEO and Co-Founder of the company.

"There are still high levels of unmet medical need for UC and CD treatment. Despite anti-TNF agents being entrenched in the treatment of UC and CD, there remains a significant number of patients who lose response to these biological drugs. The high cost of using these biologics is another issue," noted Dr Aik Han Goh, Reistone's Chief Medical Officer. "Small molecule drugs, such as SHR0302, potentially provide a new alternative treatment resolution for the patients."