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Ascletis completes bridging study of ASC18

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The study of ASC18, first one-pill, once-a-day fixed dose combination (FDC) as the complete hepatitis C treatment developed by China biotech



China-based Ascletis Pharma Inc. recently announced that it completed bridging study of ASC18, the first one-pill, once-a-day fixed dose combination (FDC) as the complete hepatitis C treatment.

ASC18 FDC consists of 200 mg Ravidasvir (RDV) and 400 mg Sofosbuvir (SOF). This ph I bridging study was a randomized, two arms [ASC18 FDC tablet and (RDV 200 mg + SOF 400 mg given in separate pills)], two cycles, two phases (single-dose phase and multiple-dose phase), two-sequence crossover design.

The results from this phase I bridging study (n=20 subjects) indicated that ASC18 FDC one-pill once-a-day showed comparable pharmacokinetics (PK), safety and tolerability with RDV 200 mg + SOF 400 mg given in separate pills. ASC18 FDC will further enhance Ascletis' competitiveness in HCV marketplace.

The STORM-C-1 phase II/III trial, conducted by Drugs for Neglected Diseases initiative (DNDi) and reported at the International Liver Conference in Paris on April 12, 2018, enrolled 300 HCV patients administered with separate 200 mg RDV tablet plus 400 mg SOF tablet for 12 weeks for patients without liver cirrhosis and for 24 weeks for those with compensated cirrhosis. The results showed an overall cure rate (Sustained Virological Response, SVR12) of 97%, 96% in cirrhotic subjects, and high cure rates (SVR12) across the genotypes studied: genotype 1a: 99%, 1b: 100%, 3a: 96%, 3b:100%, and 81% among the small group of genotype 6 subjects.

On July 29, 2020, Ascletis received NDA approval of its first all-oral HCV treatment (RDV/DNV Regimen) by China's National Medical Products Administration (NMPA). RDV/DNV Regimen is Ravidasvir (Asclevir®) in combination with Danoprevir (Ganovo®), demonstrating a cure rate (SVR12) of 99 % with a short treatment duration of 12 weeks in genotype 1 non-cirrhotic patients.