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Ascletis' NDA for its all-oral HCV treatment accepted by CFDA

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Ascletis has received the acceptance letter from the China Food and Drug Administration (CFDA) for Ravidasvir (RDV) new drug application (NDA).

Ravidasvir in combination with Ganovo (RDV/DNV Regimen) is the first all-oral interferon-free HCV regimen developed by a domestic company in China. Phase II/III clinical trial has shown that RDV/DNV Regimen demonstrated a cure rate of 99 % (SVR12) with a short treatment duration of 12 weeks in genotype 1 patients. In patients with baseline NS5A resistance mutations, RDV/DNV Regimen demonstrated a cure rate of 100% (SVR12).

"Ascletis was successfully listed this morning on Hong Kong Exchange as the first ever pre-revenue biotech. The NDA for our all-oral HCV regimen was accepted by CFDA in the afternoon." Jinzi J. Wu, Ph.D., Ascletis' founder, President and CEO, commented, "Two significant accomplishments on the same day reflect our unremitting effort to provide affordable and effective HCV cures to the patients and to fulfill our commitment to the investors."

The acceptance of the NDA for its all-oral HCV regimen enables Ascletis soon to provide two HCV treatment options for Chinese patients, strengthening its leading position in China's HCV field.