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Ganovo approval marks a milestone for MAH policy in China

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WuXi STA enables Ascletis to receive NDA Approval from China FDA for Ganovo (R), ASC08



Ascletis (partner of WuXi STA) receives approval from National Drug Administration of China (CNDA, former CFDA) of its Category 1 new drug, Ganovo® (also known as Danoprevir or ASC08), to treat viral hepatitis C. Ganovo® is the first Direct-acting Anti-viral Agent (DAA) developed by a domestic company in China and has been selected as a National Science and Technology Major Project for "Innovative Drug Development".

With this approval, WuXi STA became the first Contract Development and Manufacturing Organization (CDMO) to support the launch of innovative drugs in China since the implementation of Marketing Authorization Holder (MAH) pilot program.

The approval of Ganovo® marked a critical milestone in the history of the "MAH" policy in China. The collaboration between WuXi STA and Ascletis originated in 2012. Via its industry leading process development and manufacturing technology platform and global standard quality system, WuXi STA supported the process optimization and process validation of Ganovo® Active Pharmaceutical Ingredient (API) as well as the Ganovo® NDA submission and approval. In December 2017, WuXi STA's Jinshan API manufacturing site successfully passed the pre-approval inspection by CNDA as part of the Ganovo® NDA application process. As a pioneer of "MAH", WuXi STA is helping many innovative drug development partners in China including Ascletis to optimize their manufacturing processes, significantly reduce commercial production costs, mitigate business risk, and improve operational efficiency.