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China's Ascletis expands Ritonavir oral tablet production for COVID-19

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Ascletis Pharma Inc., based in China, has announced the expansion of the production of ritonavir oral tablets and oral direct-acting antiviral R&D pipeline for the treatment of SARS-CoV-2 infection.

The company's COVID-19 pipeline currently includes (i) ritonavir oral tablet (100mg), an authorized product, (ii) ASC10, an oral RNA dependent RNA polymerase (RdRp) inhibitor and (iii) ASC11, an oral 3-chymotrypsin like protease (3CLpro) inhibitor.

The company owns the only authorized ritonavir oral tablet in China, which passed bioequivalence study. The ritonavir oral tablet was approved in September, 2021 by China National Medical Products Administration (NMPA).

As a pharmacokinetic booster of multiple antiviral protease inhibitors, a low dose ritonavir oral tablet (100mg) is a component of oral direct-acting antiviral drug Paxlovid (Nirmatrelvir+ritonavir).

Ascletis is planning to file generic drug applications for registrations in multiple countries in the world. Ritonavir oral tablet annual production capacity has been expanded to 100 million tablets and can be further rapidly expanded based on market demand.

Further, the data from animal studies has demonstrated that ASC10 has higher bioavailability when compared to Molnupiravir. The company plans to submit investigational drug applications (INDs) for clinical trials in China, USA etc. in the first half of 2022.