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ASIA EDITION

Ascentage Pharma receives commercialisation approval for oncology drug in Macau China

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Olverembatinib is company's first lead asset developed for the treatment of drug-resistant chronic myeloidleukemia and the company's first approved product in China

Ascentage Pharma has announced that its novel BCR-ABL1 tyrosine kinase inhibitor (TKI), olverembatinib, has been approved by the Pharmaceutical Administration Bureau (ISAF) of the Macau Special Administrative Region (SAR) ofthe People's Republic of China for the treatment of adult patients with tyrosine kinase inhibitors (TKI)-resistant chronic-phase chronic myeloid leukemia (CML-CP) or accelerated-phase CML (CML-AP) harbouring the *T315I* mutation; and adult patients with CML-CP resistant to and/or intolerant of first-and second-generation TKIs.

This approval marks another major milestone for olverembatinib following initial approvals granted to the drug in the Chinese mainland for the above indications.

Olverembatinib, a novel drug developed by Ascentage Pharma with support from the National Major New Drug Development programme, is the first third-generation BCR-ABL1 inhibitor approved by China's National Medical Products Administration (NMPA).

As a potential global best-in-class drug that can effectively target BCR-ABL1 and a spectrum of BCR-ABL1 mutants, including the *T315I* mutation, clinical trial results of olverembatinib have already been included in the National Comprehensive Cancer Network (NCCN) guidelines for the management of CML.

Olverembatinib is being jointly commercialised in China by Ascentage Pharma and Innovent Biologics. All lead drug candidates are being studied as they are an investigational drug and not approved in the US.