



Ripretinib Becomes the First Unregistered Drug in Mainland China Approved for the Named Patient Program Outside the Pilot Zone of Hainan Province

July 30, 2020

SHANGHAI, July 30, 2020 -- Zai Lab today announced ripretinib has been approved by Health Commission and Medical Products Administration of Hainan Province as the first drug in mainland China used under the special Named Patient Program (NPP). Under the NPP, patients can now be prescribed ripretinib both inside and outside of Hainan Province (the Pilot Zone).

The special NPP was enacted in 2013 to address the urgent unmet medical needs for medical devices and drugs approved in the U.S., EU or Japan but not yet approved by the China National Medical Products Administration (NMPA) in mainland China. Under this program, those medical devices and drugs with urgent unmet medical needs can be imported via special approval procedures and used in the designated Pilot Zone of Hainan Province based on individual patient requests.

In March of this year, an expanded policy was released to allow patients not only to use the unregistered drugs in the Pilot Zone, but also outside the Pilot Zone following strict protocols. Ripretinib becomes the first drug following the expansion of the policy to outside the Pilot Zone. Zai Lab has designed a comprehensive patient management protocol to ensure safety of all patients approved under the NPP.

In May, ripretinib was granted full approval by the U.S. Food and Drug Administration (FDA) for the treatment of fourth-line gastrointestinal stromal tumor (GIST). Ripretinib is also approved by Health Canada and the Australian Therapeutic Goods Administration. On July 20, 2020, the NMPA accepted the New Drug Application for ripretinib for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib.