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Korea FDA accepts IND application from Hanmi

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Korea FDA accepts IND application by Hanim for KX-01

Singapore: Korean Food and Drug Administration (KFDA) has accepted Hanmi Pharmaceutical's investigational new drug application for KX-01, dual src/pretubulin inhibitor by Kinex Pharmaceuticals, in the oncologic setting. The data package included Kinex's preclinical and clinical data for KX-01, as well as Hanmi's preclinical gastric cancer data.

KX01 differentiates itself as an inhibitor that targets the kinase substrate pocket and therefore offers an excellent efficacy as well as safety profile. In addition, KX01 has potent inhibitory activity against pre-tubulin. KX01 has been shown to be very effective against a broad range of cancers in both in vitro experiments and in animal cancer models. Importantly, the compound has synergistic/additive activities with a number of first line chemotherapeutic agents. A completed phase I study, in patients with end-stage cancer, showed a desirable safety profile and stable disease or clinical response in approximately 25 percent of the patients. Proof-of-concept studies are ongoing. The composition of matter of KX01 is covered by issued patents.

Dr Gwan-Sun Lee, president and CEO of Hanmi, said, "This is another important milestone in our successful partnership with Kinex. This also demonstrates our growing focus and commitment to oncology therapeutics."

"This is a major step forward," added Dr Jeewoong Son, senior VP and head of Innovation R&D at Hanmi. "The close collaboration between our scientific teams has helped define our initial development strategy. Kinex is a great partner and continues to show strong support. We will continue focus our efforts on unmet oncology needs together."

"Kinex is pleased to be working with such a committed partner," commented Dr Lyn Dyster, SVP of Operations. "Hanmi's ability to work with their local regulatory bodies to advance the KX01 development program in Korea is a critical step in our overall development strategy."

Dr Rudolf Kwan, CMO of Kinex, stated, "The acceptance of Hanmi's IND by the Korean FDA is a crucial piece of our mutual development plans and will generate important clinical data for both parties soon. Kinex will also pursue additional development pathways to broaden KX-01's potential utility."

Kinex is also developing oral forms of Paclitaxel and Irintotecan, both are in clinical stages of development, through a licensing agreement with Hanmi Pharmaceuticals. Kinex is also developing KX02 for brain tumors with Xiangxue Pharmaceuticals based in Guangzhou, China.