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Kinex Oraxol IND application gets FDA nod

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Singapore: Kinex Pharmaceuticals has got approval from the US FDA for its Investigational New Drug (IND) application for Oraxol, which allows for oral delivery of paclitaxel when combined with Hanmi Pharmaceutical's absorption enhancer, HM30181A.

Kinex has global development and commercialization rights for Oraxol, excluding Korea, Japan and India that are owned by Hanmi, and New Zealand and Australia which were recently licensed to Zenith Technology. Kinex, Hanmi and ZenRx will jointly develop Oraxol globally through a collaborative effort. Oraxol is Kinex's second IND to be allowed this year and the company will proceed to Phase I/Ib clinical protocols as planned.

Oraxol is only one of many compounds that could be developed by Kinex and Hanmi through the Orascovery program. Orascovery is based on an important platform technology developed by Hanmi Pharmaceuticals using compound HM30181A, a potent and selective P-glycoprotein (PGP) pump inhibitor. Suppression of the PGP pump allows certain clinically important compounds (such as paclitaxel, irinotecan, and others), which would normally be effluxed back into the gastrointestinal tract and excreted, to enter the bloodstream and become bioavailable through oral administration. Importantly, HM30181A is a very potent PGP inhibitor that is not systemically absorbed.

Dr. Lyn Dyster, senior VP, operations, Kinex, said that, "Working with the Hanmi team on the Oraxol IND has been terrific. Their expertise and dedicated team, combined with our internal efforts, lead to a timely IND submission. Given that Hanmi is in phase II in Korea, their extensive preclinical and clinical knowledge of the compound was invaluable to our efforts. Oraxol is an important program for both companies and we are excited to move forward with our clinical programs in the US."

Dr Gwan Sun Lee, CEO, Hanmi Pharmaceutical, said that, "The Kinex team moved the IND process forward in a precise and expert manner. This is another major step forward in the collaboration between Kinex and Hanmi. I believe that as part of our global growth strategy, our partnership with Kinex will benefit Hanmi by providing participation in major markets outside of our traditional territories. US and New Zealand clinical trials are an important example of that opportunity. We have great confidence in the Kinex team and our expanding relationship."