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NiKang Therapeutics Doses First Patient in a Phase 1/1b Study of NKT3447, an Oral, Selective Inhibitor of CDK2 Which Reduces Cyclin E Expression

- Highly selective and unique cyclin E-reducing CDK2 inhibitor designed to treat patients with cyclin E amplified cancers being evaluated in patients with selected solid tumors driven by cyclin E or CDK2 -

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WILMINGTON, Del.--(BUSINESS WIRE)--NiKang Therapeutics Inc. (“NiKang”) is a clinical stage biotech company focused on developing innovative small molecule oncology medicines to help patients with unmet medical needs. The Company announced today that the first patient has been dosed in a phase 1/1b, open-label, first-in-human dose escalation and expansion study of single agent NKT3447, a small molecule that inhibits cyclin-dependent kinase 2 (CDK2). NKT3447 is designed to treat patients with cancers driven by cyclin E amplification or overexpression, which is present in many different tumor types.

The Phase 1/1b trial (NCT06264921) is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical activity of NKT3447 in adult patients with advanced or metastatic solid tumors driven by cyclin E or CDK2.

“The initiation of dosing in this study marks a major milestone for NiKang, as NKT3447 is the first of our pipeline programs targeting the cell cycle to begin clinical evaluation,” said Zhenhai Gao, Ph.D., co-founder, president, and CEO of NiKang. “We have strong conviction that CDK2 is a key oncology target and have taken a holistic approach to build an industry-leading portfolio that also includes a CDK2-selective degrader and a CDK2/4 dual degrader. While there has been clinical success with drugs targeting the cell cycle, it has been challenging to identify inhibitors of CDK2 that spare CDK1 and do not cause a compensatory increase of cyclin E which is a driver of tumor cell proliferation. NKT3447 binds inactive monomeric CDK2, disrupting the CDK2/cyclin E complex without impacting CDK1. Furthermore, its interaction with CDK2 results in suppression of activating phosphorylation of CDK2 on Thr160 and a substantial downregulation of cyclin E, potentially preventing a mechanism of resistance.”

“We are excited to initiate clinical trials of NKT3447, which has unique features that have led to sustained pharmacodynamic effects and significant anti-tumor activity in various cyclin E amplified tumor models,” said Joanne Jenkins Lager, M.D., Chief Medical Officer of NiKang. “CDK2 and cyclin E are deregulated in many human cancers, and we believe NKT3447 has the potential to change the standard of care for people with cyclin E amplified or overexpressing cancers including ovarian cancer, endometrial cancer and gastric cancer.”

About NiKang Therapeutics

NiKang Therapeutics is a clinical stage biotech company focused on discovering and developing innovative small molecule oncology medicines to help patients with unmet medical needs. Our target selection is driven by deep insight into disease biology and molecular pathways. Our discovery approach is informed by target structure biology and

capitalizes on structure-based drug design. The successful implementation of our strategy enables us to rapidly and efficiently discover and advance proprietary drug candidates with the most desirable pharmacological features into clinical studies. We strive to bring transformative medicines to patients in need.

For more information, please visit http://www.nikangtx.com

Contacts

Kelsey Chen
Chief Financial and Operating Officer
IR@nikangtx.com

Social Media Profiles

NiKang Therapeutics