

Media & Publications

Press Releases

NIKI PHARMA ANNOUNCES POSITIVE INTERIM DATA FROM ONGOING CLINICAL TRIAL OF NOVEL ANTI-CANCER AGENT NKP-1339

HOBOKEN, N.J. and PHILADELPHIA, Sept. 20, 2011 /PRNewswire/ -- Niiki Pharma Inc. announced interim results from the ongoing Phase I clinical trial of its lead product, NKP-1339. NKP-1339 is a first-in-class transferrin targeted small molecule that down-regulates GRP78, a key regulator of mis-folded protein processing and a tumor survival factor.

NKP-1339 Phase I Interim Data

The Phase I trial is conducted in patients with metastatic solid tumors resistant to standard therapies. Previous to enrollment in the trial, all patients had received multiple standard therapies and exhibited disease progression on their last treatment. Of the first 24 patients enrolled, six patients (25%) exhibited anti-tumor activity, demonstrated by disease stability and/or tumor regression for at least 12 weeks.

Of the responding six patients, one patient with carcinoid tumor, a non-pancreatic neuroendocrine tumor (non-pNET), has tumor regression and continues on NKP-1339 therapy for more than 70 weeks. The five other patients have experienced stable disease of up to 24 weeks with NKP-1339 treatment. These patients have the following tumor types: one gastrinoma non-pNET, one colorectal cancer, two non-small cell lung cancers and one cancer of unknown primary.

NKP-1339 treatment has been well tolerated to date with mild manageable side effects. The most common drug-related side effects are grade 1-2 fever and mild flu-like symptoms, which can be prevented with standard medications. The maximum tolerated dose has not been reached and NKP-1339 dose escalation continues.

The trial is being led by Dr. Daniel Von Hoff, Virginia G. Piper Cancer Center Clinical Trials at Scottsdale Healthcare in partnership with Translational Genomics Research Institute (TGen), and Dr. Howard Burris, Director of Drug Development at the Sarah Cannon Research Institute (SCRI).

"We need new treatments for patients with non-pNET. The NKP-1339 anti-tumor activity observed in these two non-pNET patients is significant. This activity, together with mild-side effect profile, makes NKP-1339 a potentially promising new treatment for this disease," said Dr. Daniel Von Hoff.

"It is gratifying to see someone whose tumor has been resistant to other therapies do well with this promising investigational therapy. The patient has received NKP-1339 for more than a year and continues to benefit," added Dr. Howard Burris.

"We are pleased by these interim results demonstrating the single agent anti-tumor activity of NKP-1339 in patients with advanced cancers refractory to standard treatments," said Dr. Angela Ogden, Chief Medical Officer for Niiki Pharma Inc.

"The preliminary results of this ongoing trial, showing the anti-tumor activity and the safety profile of NKP-1339, support our preclinical studies that the drug targets tumors selectively and is active against different tumors. We are delighted to see years of research come to fruition in collaboration with Niiki Pharma's team," said Professor Keppler, University of Vienna, inventor of NKP-1339.

About NKP-1339

NKP-1339 is a first-in-class transferrin targeted ruthenium-based anti-cancer compound. Transferrin receptor is significantly over-expressed in many tumor types. The intracellular target pathways of NKP-1339 include down-regulation of GRP78, a key regulator of mis-folded protein processing and a tumor survival factor. GRP78 is the cause of resistance in many tumor types. In preclinical studies, NKP-1339 has demonstrated activity against multiple tumor types, including those resistant to other anti-cancer agents, including platinum-containing agents, anthracyclines and anti-tubulins.

NKP-1339 was invented by Professor Bernhard K. Keppler, currently the Dean of the Faculty of Chemistry at University of Vienna, Austria, and Head of the Research Platform "Translational Cancer Therapy Research", a multi-disciplinary collaboration between University of Vienna and the Medical University of Vienna. Professor Keppler is a member of the Vienna Board of Trustees for Innovative and Interdisciplinary Cancer Research, the current President of the Austrian Association of University Professors, and a founding member of the Central European Society of Anticancer-Drug Research.

He is on the Editorial Boards of several scientific journals, including: Anticancer Research, Chemical Monthly, Bioinorganic Chemistry and Applications, Journal of Inorganic Biochemistry (2005-2009) and Current Chemical Biology.

About NKP-1339 Phase I Trial Principal Investigators

Dr. Daniel Von Hoff, M.D., F.A.C.P., is the Physician-in-Chief and Distinguished Professor at Virginia G. Piper Cancer Center Clinical Trials, at Scottsdale Healthcare in partnership with TGen in Phoenix, Arizona, and the Chief Scientific Officer for US Oncology. He was appointed to and served six years on President Bush's National Cancer Advisory Board and was past President of the American Association for Cancer Research (AACR) a former Board member of the American Society of Clinical Oncology (ASCO), and the 2010 recipient of the David A. Karnofsky Memorial Award by ASCO for his outstanding achievements in cancer research.

Dr. Howard Burris, M.D., F.A.C.P., is the Director of Drug Development for SCRI, a Nashville, Tennessee, global clinical research organization focusing on advancing therapies and accelerating drug development in areas such as oncology, cardiology and gastroenterology and a member of Tennessee Oncology. He is also a member of the ASCO Ethics, Clinical Practice and Program Committees, Board member of Gilda's Club, Past-President and Trustee for the Southern Association of Oncology, and Editor of the Oncology Report.

About Niiki Pharma Inc.

Niiki Pharma Inc. is an oncology therapeutics development company, which is focused on development of targeted first-in-class treatments for cancer.

Links

Niiki Pharma Inc. www.niikipharma.com

Dr. Daniel Von Hoff, Tgen www.tgen.org

Dr. Howard Burris, SCRI www.sarahcannonresearch.com

Professor Bernhard K. Keppler, University of Vienna <http://anorg-chemie.univie.ac.at>

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