

Novel First-in-class Anti-Cancer Agent in Development by Niiki Pharma Shows Promising Phase I Results

- Phase I data for NKP-1339, a first-in-class transferrin targeted anti-cancer agent to be presented at upcoming American Society of Clinical Oncology Annual Meeting

Hoboken, NJ and Philadelphia, PA, June 1, 2011 – Niiki Pharma announced today that it will present interim data from the ongoing Phase I clinical study for its lead product, NKP-1339, at the 2011 American Society for Clinical Oncology meeting in Chicago, IL. NKP-1339 is a novel transferrin targeted ruthenium based anti-cancer compound. The intracellular targets of NKP-1339 include GRP78, a key regulator of mis-folded protein processing. In preclinical studies, in vivo and in vitro activity has been demonstrated against multiple tumor types, including those resistant to other anti-cancer agents.

The NKP-1339 Phase I trial is a dose-ascending trial and determines the safety, tolerability, maximum tolerated dose (MTD) and pharmacokinetics of NKP-1339. A total of 16 patients with metastatic solid tumors resistant to standard therapies have been treated to date at 6 different dose levels. NKP-1339 treatment has been generally well tolerated, with the most common drug related side effects of grade 1-2 fever and mild flu-like symptoms. MTD has not been reached and NKP-1339 dose escalation continues. Signs of anti-tumor activity (stable disease \geq 4 months; tumor regression) have been observed. A patient with a neuroendocrine tumor (NET) of small intestine has been on NKP-1339 therapy for 13+ months with a continuing minor response. The patient remains on NKP-1339 therapy. Another patient with the metastatic gastrinoma NET exhibited 6 months stable disease, and two patients with metastatic non-small cell lung cancer exhibited 4 months stable disease.

The NKP-1339 Phase I trial is being led by Dr. Daniel Von Hoff, Translational Genomics Research Institute, Arizona, and Dr. Howard Burris, Sarah Cannon Research Institute, Tennessee. Reflecting on NKP-1339's novel mechanism of action, Dr. Von Hoff noted "Resistance to anticancer therapy remains a major challenge in treatment of patients with metastatic cancer. First-in-class drugs, like NKP-1339, can take us one step further to address this high unmet need". While Dr. Burris commented, "The results to date, indicate that NKP-1339 could be a promising new agent that would enhance our anti-cancer armamentarium".

About Niiki Pharma

Niiki Pharma Inc is an oncology therapeutics development company with a pipeline of novel targeted anti-cancer agents. For more information, visit www.niikipharma.com.

About Translational Genomics Research Institute

The Translational Genomics Research Institute (TGen) is dedicated to conducting groundbreaking research with diseases such as cancer, neurological disorders and diabetes. For more information, visit www.tgen.org.

About Sarah Cannon Research Institute

Sarah Cannon Research Institute (SCRI) is a global clinical research organization focusing on advancing therapies and accelerating drug development in areas such as oncology, cardiology and gastroenterology. For more information, visit <http://sarahcannonresearch.com>.

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