

Niiki Pharma Announces the Completion of Phase I Dose Escalation for First-in-Man Anti-Cancer Agent NKP-1339

Trial Demonstrates Favorable Safety Profile with Anti-Tumor Activity

HOBOKEN, N.J. and PHILADELPHIA, Jan. 17, 2012 /PRNewswire/ -- Niiki Pharma Inc. announced today that it has completed the dose escalation portion of the Phase I clinical trial of its lead product, NKP-1339. NKP-1339 is a first-in-class small molecule that down-regulates GRP78, a key tumor survival and anti-apoptosis factor.

The NKP-1339 single agent dose escalation Phase I trial was conducted in patients with advanced solid tumors resistant to multiple, standard therapies. NKP-1339 was administered intravenously once weekly for 3 weeks followed by one week of no treatment. Thirty-four patients were treated, of which 30 were evaluable for dose determination. The NKP-1339 Phase I 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, and Dr. Howard Burris, at the Sarah Cannon Research Institute.

The NKP-1339 dose limiting toxicity was grade 2-3 nausea and grade 1-2 reversible renal insufficiency. At the recommended Phase II dose, NKP-1339 treatment was generally well tolerated and had manageable side effects. The most common drug-related side effects were grade 1 nausea, grade 1-2 vomiting and grade 1-2 fatigue. Infusional fever and chills were noted but prevented with steroid premedication.

"We reached our goal to determine the dose of NKP-1339 to take forward in future trials. Many toxicities commonly associated with other anticancer drugs, such as neutropenia, hepatotoxicity, neuropathy, rash, mucositis, diarrhea and alopecia, have not been seen to date," said Dr. Burris.

Anti-tumor activity, demonstrated by disease stability and/or tumor regression for 12-88+ weeks, was noted in patients with neuroendocrine tumors (NET), non-small cell lung cancer, sarcoma, colorectal and cancer of unknown primary. Three patients continue to receive NKP-1339 therapy on study.

"The preliminary read of NKP-1339 anti-tumor activity in this advanced cancer patient population shows evidence of activity in patients with NET," commented Dr. Von Hoff.

"We are excited with the prospects for NKP-1339 in NET, an orphan indication which is presently highly underserved. NKP-1339 trials in this indication are in development. In addition the favorable NKP-1339 safety profile supports plans to evaluate NKP-1339 in combination regimens in other tumor types," said Angela Ogden, M.D., Chief Medical Officer at Niiki Pharma.

About NKP-1339

NKP-1339 is a first-in-class small molecule anti-cancer compound. NKP-1339 down-regulates GRP78, a key regulator of mis-folded protein processing and a tumor survival and anti-apoptosis factor. Up-regulation of GRP78 is associated with intrinsic and chemotherapy-induced 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. NKP-1339 was discovered by Professor Bernhard Keppler, University of Vienna, Austria.

About Niiki Pharma Inc.

Niiki Pharma (www.niikipharma.com) is a development focused oncology company specializing in first-in-class cancer treatments directed at novel tumor targets and related companion diagnostics.

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