

Niiki Pharma Breaks New Ground with Novel Cancer Therapy

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A first-in-man cancer therapy in development by Niiki Pharma Inc. shows promise in targeting a new pathway known as GRP78. This target repairs damaged or deconstructed proteins that result from rampant tumor cell growth. Normal healthy cells have low levels of GRP78. Cancer cells require very high levels of GRP78 and become, in effect, "addicted" to GRP78 for their survival. Known as NKP-1339, Niiki Pharma's compound is an entirely new chemical entity that down regulates GRP78, thus shutting down the tumor cell's key survival mechanism.

"There is a growing body of medical literature that identifies GRP78 as a target for cancer therapies", Dr. Angela Ogden, MD, Chief Medical Officer at Niiki Pharma, explained in a recent interview with the Philadelphia Business Journal. "Nobody, other than Niiki, has a drug targeting GRP78. Now companies are starting to look at developing molecules to block it, but those are years away from getting into patients."

Anti-Tumor Activity and Favorable Safety Profile Leads to Phase IIa Clinical Trial

Niiki Pharma recently completed a Phase I trial and has determined the dose for a Phase II trial. The trial was conducted in patients with metastatic cancers that had failed all standard treatments. At the recommended Phase II dose, NKP-1339 treatment is generally well tolerated with manageable side effects.

Summary results of the Phase I trial show that 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. The effect of NKP-1339 on neuroendocrine tumors is noteworthy as there currently is no effective therapy available for the second most prevalent tumor type of the GI tract.

Promising Synergistic Activity with Other Anti-Cancer Agents

High levels of GRP78 in cancer cells have been correlated with drug resistance in numerous tumor types. Treatment with many anti-cancer agents further induces GRP78, which boosts the tumor cells resistance to the treatment. Anti-cancer agents that induce GRP78 include platinum, taxanes, anthracyclines, anti-metabolites, proteasome inhibitors and kinase inhibitors.

"We are quite pleased with the development of NKP-1339. The early activity that we have seen [NKP-1339 single agent] in neuroendocrine tumors naturally leads us to pursue further development in this orphan indication. We are also very excited about the development of NKP-1339 in combination with standard anticancer agents for several additional tumor types. In parallel to our clinical development, we are developing a companion diagnostic so that NKP-1339 therapy can be targeted to those who will derive the greatest benefit", added Dr. Ogden. NKP-1339 Phase I dose escalation results has been submitted for presentation at the American Society of Clinical Oncology (ASCO) 2012.