NEWGEN THERAPEUTICS, INC.
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NewGen Therapeutics Presents Data on NT-113, A Novel Pan-ErbB Inhibitor, at American Association of Cancer Research

NT-113 is an Irreversible, Selective Pan-ErbB Tyrosine Kinase Inhibitor with Significant Capacity to Cross Blood Brain Barrier

MENLO PARK, CA (April 8, 2013) – Preclinical data showing high potency, excellent pharmacokinetics and single-agent anti-cancer activity of NT-113, a novel irreversible Pan-ErbB Tyrosine Kinase Inhibitor under development by NewGen Therapeutics, was presented in a poster session today at the American Association of Cancer Research Meeting in Washington, D.C.

Data showed that NT-113 is a very potent inhibitor of ErbB subtypes, including EGFR, HER2 and ErbB4, in a panel of over 100 tyrosine kinases and is highly active against erlotinib (Tarceva®) and gefitinib (Iressa®) resistant cancer cells with EGFR mutations including T790M, L858R, and d-746-750. Potent anti-cancer activity was demonstrated in T790M mutant non-small cell lung (NSCLC) cancer and HER2 positive gastric cancer xenograft models. Pharmacokinetic data showed excellent oral bioavailability, a long half-life and the ability to penetrate the blood barrier at therapeutic concentrations.

In collaboration with C. David James, Ph.D., University of California, San Francisco (UCSF), NT-113 was studied for both in vitro and in vivo for activity in glioblastoma (GBM). NT-113 showed a broad spectrum of in vitro activity across multiple human GBM cell lines. In addition, data showed statistically significant anti-cancer activity and increase in survival relative to a control group in an intracranial GBM39 mouse xenograft model. GBM39 is a human GBM cell line that carries the disease driving EGFRvIII mutation.

Key differentiating features of NT-113 include:

- Equipotency across EGFR, HER2 and ErbB4
- Excellent distribution of NT-113 into the brain at therapeutic doses (4:1 brain/plasma concentrations)
- Excellent oral bioavailability and pharmacokinetics
- Potency against the distinct EGFR mutations found in both GBM and other solid tumors including extra-cranial malignancies such as NSCLC, breast cancer and melanoma
- Demonstrated potent anti-cancer activity in an HER2 positive gastric cancer, T790M mutant NSCLC and GBM39 intracranial mouse xenograft studies

“These unique differentiating attributes have the potential to make NT-113 the preferred treatment for patients with malignancies that over-express members of the ErbB family, including GBM, NSCLC, breast cancer, gastric cancer, colon cancer, head and neck cancer, and melanoma,” commented Harry D. Pedersen, President and Chief Executive Officer. “Over 90% of solid tumors over-express at least one ErbB receptor. Agents targeting single receptors in the family, including Iressa®, Herceptin®, Erbitux® and Tarceva®, have made a significant impact on survival in a number of cancers and account for billions of dollars in annual sales. A single agent that targets all receptors in the family should result in better overall clinical outcomes.”

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"Moreover, NT-113's remarkable ability to cross the blood brain barrier suggests it could be particularly beneficial to patients with GBM or brain metastases from susceptible primary cancer types. While current agents that target individual ErbB receptors have high clinical response rates and significant increases in survival, patients frequently progress with brain metastases. Since no other currently approved ErbB inhibitors cross the blood brain barrier, NT-113 has the potential to be a major advancement in the treatment of cancers that over-express one of the ErbB receptors and tend to metastasis to the brain. Our plan is to initially focus on GBM, where EGFR is a validated target and we have a chance for an accelerated approval within five years, and to eventually expand into other solid tumors that over-express EGFR and tend to metastasize to the brain."

Mr. Pedersen noted that NT-113 and additional analogs are currently in preclinical development, and that NewGen expects to file an Investigational New Drug (IND) application to begin clinical trials with NT-113 in 2014.

About NewGen

NewGen Therapeutics is a privately held pharmaceutical company developing patient-targeted cancer drugs that are designed to overcome limitations of currently available therapies. The company's pipeline includes multiple programs with novel small molecule drug leads against clinically important targets, each addressed to significant medical needs. NT-113, a potent irreversible pan-ErbB inhibitor, is the company's most advanced program and has demonstrated anti-cancer activity in several cancer xenograft studies, including GBM, gastric cancer and NSCLC. NT-113 will enter Phase 1 clinical trials in 2014. In addition, NewGen's pipeline includes NT-004, a reversible pan-ErbB inhibitor and NT-125, a PARP inhibitor, both in late preclinical development

NewGen's strategy is to identify and in-license promising programs, add value through further development and then partner with pharmaceutical companies for clinical development and commercialization. For more information, please visit our website at: http://www.newgenther.com.

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