

NewGen Therapeutics Targeted Anti-Cancer Drug, NT-113, Demonstrates Compelling Activity in Glioblastoma Xenograft Models

- **Novel irreversible pan-erbB inhibitor is active against patient-derived GBM xenografts overexpressing EGFR, including the disease-driving EGFRvIII mutation**
- **Demonstrates significant improvement in survival, tumor growth inhibition compared to lapatinib and/or erlotinib**
- **Clinical trials expected to begin in early 2016**
- **Findings published in *Molecular Cancer Therapeutics***

MENLO PARK, CA (December 15, 2014) -- [NewGen Therapeutics, Inc.](http://www.newgen.com) today announced the publication of preclinical research strongly supporting NT-113, the company's novel irreversible pan-erbB inhibitor (EGFR, HER2 and HER4), as a potential new treatment for glioblastoma multiforme (GBM), the most common and most aggressive malignant primary brain tumor in adults.

Researchers demonstrated that NT-113 was active against a variety of patient-derived GBM xenografts in which EGFR is amplified, overexpressed and/or expresses the disease-driving EGFRvIII mutation. In studies of intracranial mouse xenografts comparing NT-113 to the approved anticancer therapeutics lapatinib and/or erlotinib, NT-113 was associated with statistically significant improvement in survival. NT-113 both reduced tumor cell proliferation and induced apoptosis (controlled cell death). In previous pharmacokinetic studies, NT-113 demonstrated a long half-life and a high propensity to cross the blood brain barrier.

Researchers concluded that the pan-erbB inhibitory activity of NT-113 and downstream inhibition of Akt provide mechanistic rationale for its heightened anti-tumor activity. Excellent bio-distribution into the brain is also believed to contribute to the anti-GBM xenograft activity of NT-113. NT-113 was active in other GBM xenograft studies including one in which the cells are PTEN deficient, a known resistance mechanism for EGFR inhibitors, and another where cells overexpress both EGFR and HER2. Data support advancing NT-113 into clinical development for the treatment of erbB positive GBM, including patients with the disease driving EGFRvIII mutation.

The findings by NewGen and the company's collaborators at Northwestern University and The University of California, San Francisco and the Mayo Clinic were published in the [December 2014 issue](#) of ***Molecular Cancer Therapeutics***.

Harry D. Pedersen, NewGen Therapeutics President and Chief Executive Officer commented, "EGFR, HER2 and HER4 are part of the erbB family of tyrosine kinase receptors, and 90% of solid tumors have a mutation in at least one erbB receptor family member. By irreversibly inhibiting all family members we hope to shut down the individual receptors and the cooperative signaling between family members associated with resistance."

NT-113 readily penetrates the blood brain barrier resulting in 4-8 times drug concentration in the brain relative to plasma. First-generation EGFR inhibitors like erlotinib and lapatinib are reversible and have very limited penetration of the central nervous system.

“GBM is a molecularly complex disease with significant unmet medical need: over 50% of patients have genetic alterations in EGFR or HER2,” Mr. Pedersen said. “These data provide a strong rationale for the clinical investigation of NT-113 in this patient population. We anticipate beginning clinical trials in early 2016.”

About NT-113

NT-113 is a potent oral irreversible pan-erbB inhibitor designed specifically to:

- Target mutations in both the extracellular domain of EGFR (characteristic of GBM) and the intracellular domain of EGFR (characteristic of other tumours such as NSCLC),
- Improve drug delivery into the brain to optimize drug delivery and treatment of patients with primary glioblastoma or brain metastases from an EGFR driven extracellular primary,
- Overcome resistance to first generation erbB inhibitors by targeting redundancy in the pathway, and
- Improve the efficacy of erbB-targeted therapies by irreversibly inhibiting multiple erbB receptors, and interfering with the cooperation that exists between receptors.

About NewGen

NewGen Therapeutics is a privately held pharmaceutical company developing genetically 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 glioblastoma, non-small cell lung, breast and gastric cancers. For more information, please visit our website at <http://www.newgenther.com>.

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