



**FOR IMMEDIATE RELEASE**

**NOVELOS THERAPEUTICS ENROLLS FIRST PATIENT IN PHASE 1b TRIAL  
IN SOLID TUMORS WITH <sup>131</sup>I-CLR1404 (HOT) CANCER-TARGETED  
MOLECULAR RADIOTHERAPEUTIC**

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*Expects to Begin Phase 2 Proof-of-Concept Trials in First Quarter of 2013*

**MADISON, WI, January 17, 2012** – Novelos Therapeutics, Inc. (OTCBB: NVLT), a pharmaceutical company developing novel drugs for treatment and diagnosis of cancer, today announced that it has enrolled the first patient in a U.S. multi-center Phase 1b dose-escalation trial of its cancer-targeted molecular radiotherapeutic compound <sup>131</sup>I-CLR1404 (HOT) in cancer patients with advanced solid tumors. Details of the trial design are available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) ID: NCT01495663, or at [www.novelos.com](http://www.novelos.com) in the 'Clinical Trials' section. Glenn Liu, M.D., University of Wisconsin Carbone Cancer Center, is the trial's principal investigator.

"Patients with advanced solid tumors need new, safer and more effective therapies," said Dr. Liu. "Based on animal data and initial data from a Phase 1a dosimetry trial, HOT appears to deliver radiation directly and selectively to tumors and cancer stem cells."

"The data from this trial will be combined with calculation of effective doses for HOT based on quantitative positron emission tomography (PET) tumor imaging data using LIGHT, our small-molecule cancer-targeted PET imaging agent," said Harry Palmin, President and CEO of Novelos. "Together, we believe this combination will enable us to commence HOT Phase 2 proof-of-concept trials in the first quarter of 2013 in advanced cancer patients with significant unmet medical need."

**About HOT**

HOT (iodine-131 radiolabeled CLR1404) is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that we believe has first-in-class potential. HOT is comprised of a small, non-pharmacological quantity of CLR1404 (COLD) acting as a cancer-targeted delivery and retention vehicle and incorporating a cytotoxic dose of radiotherapy (in the form of iodine-131, a radioisotope that is already in common use to treat thyroid and other cancer types). It is this "intracellular radiation" mechanism of cancer cell killing, coupled with selective delivery to a wide range of malignant tumor types that imbues HOT with broad-spectrum anti-cancer activity. Selective uptake and retention has also been demonstrated in cancer stem cells compared with normal stem cells, offering the prospect of longer lasting cancer remission. In 2009 we filed an IND with the FDA to study HOT in humans. In early 2010 we successfully completed a Phase 1a dosimetry trial demonstrating initial safety, tumor imaging and pharmacokinetic consistency and establishing a starting dose for a Phase 1b dose-escalation trial. The ongoing Phase 1b dose-escalation trial is aimed at determining the Maximum Tolerated Dose of HOT. We expect to initiate HOT Phase 2 efficacy trials as a monotherapy for solid tumors with significant unmet medical need as soon as a minimal efficacious dose is established. We may determine such an effective dose upon seeing a tumor response in the Phase 1b trial or calculating it from ongoing PET imaging trials in cancer patients with LIGHT. Preclinical *in vitro* (in cell culture) and *in*



*vivo* (in animals) experiments have demonstrated selective killing of cancer cells along with a benign safety profile. HOT's anti-tumor/survival-prolonging activities have been demonstrated in more than a dozen xenograft models (human tumor cells implanted into animals) including breast, prostate, lung, glioma (brain), pancreatic, ovarian, uterine, renal and colorectal cancers and melanoma. In all but two models, a single administration of HOT was sufficient for efficacy. In view of HOT's selective uptake and retention in a wide range of solid tumors and in cancer stem cells, its single-agent efficacy in xenograft models and its non-specific mechanism of cancer-killing (radiation), we expect first to develop HOT as a monotherapy, initially for solid tumors.

#### **About Novelos Therapeutics, Inc.**

We are a pharmaceutical company developing novel drugs for the treatment and diagnosis of cancer. Our three cancer-targeted compounds are selectively taken up and retained in cancer cells (including cancer stem cells) versus normal cells. Thus, our therapeutic compounds appear to directly kill cancer cells while minimizing harm to normal cells. This offers the potential for a paradigm shift in cancer therapy by providing efficacy versus all three major drivers of mortality in cancer: primary tumors, metastases and stem cell-based relapse. LIGHT is a small-molecule cancer-targeted PET imaging agent. We believe LIGHT has first-in-class potential and Phase 1-2 clinical trials are ongoing. HOT is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that delivers radiation directly and selectively to cancer cells and cancer stem cells. We believe HOT also has first-in-class potential. HOT Phase 1b dose-escalation trial is ongoing and we expect HOT to enter Phase 2 trials in the first quarter of 2013 as monotherapy for solid tumors with significant unmet medical need. COLD, a cancer-targeted non-radioactive chemotherapy, works primarily through Akt inhibition. We plan to file an IND for COLD in the first quarter of 2013. Together, we believe our compounds are able to "find, treat and follow"<sup>TM</sup> cancer anywhere in the body in a novel, effective and highly selective way. For additional information please visit [www.novelos.com](http://www.novelos.com)

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This news release contains forward-looking statements. You can identify these statements by our use of words such as "may," "expect," "believe," "anticipate," "intend," "could," "estimate," "continue," "plans," or their negatives or cognates. Such statements are valid only as of today, and we disclaim any obligation to update this information. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement.

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