

## **Novelos**

# **Novelos Therapeutics Discontinues Current Development Program for NOV-002 in NSCLC**

NOV-002 Phase 2 Development Continues in Breast Cancer Indication; Seeking to Build Clinical Stage Oncology Pipeline

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NEWTON, Mass.--(<u>BUSINESS WIRE</u>)--Novelos Therapeutics, Inc. (OTCBB: NVLT), a biopharmaceutical company focused on the development of therapeutics to treat cancer and hepatitis, today announced that primary and secondary endpoints were not met in Novelos' pivotal Phase 3 trial in advanced non-small cell lung cancer (NSCLC) with its lead product, NOV-002, in combination with first-line chemotherapy. Adding NOV-002 to paclitaxel and carboplatin chemotherapy was not statistically or meaningfully different in terms of efficacy-related endpoints or recovery from chemotherapy toxicity versus chemotherapy alone. NOV-002 was safe, as it did not add to the overall toxicity of chemotherapy. Detailed trial results are expected to be presented at the 2010 annual meeting of the American Society of Clinical Oncology (ASCO) taking place June 4-8 in Chicago, Illinois.

This randomized, controlled, open-label Phase 3 trial, conducted under a Special Protocol Assessment (SPA) and Fast Track designation, enrolled 903 patients with Stage IIIb/IV NSCLC and included all histological subtypes. The trial encompassed approximately 100 clinical sites in 12 countries and evaluated NOV-002 in combination with first-line paclitaxel and carboplatin chemotherapy versus paclitaxel and carboplatin alone. The primary efficacy endpoint of the trial was improvement in overall survival. Secondary endpoints included progression free survival, response rate and duration of response, recovery from chemotherapy-induced myelosuppression, determination of immunomodulation, quality of



life and safety. Based on results from this Phase 3 trial, Novelos will discontinue development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy.

"We designed and executed a robust Phase 3 NSCLC trial, but disappointingly, NOV-002 did not work in this very difficult to treat indication in combination with this chemotherapy," said Harry Palmin, President and CEO of Novelos. "Moving forward, our Phase 2 programs continue in cancer and hepatitis with our oxidized glutathione-based compounds. We expect results from an ongoing NOV-002 Phase 2 breast cancer trial in 3Q 2010, and are scheduled to present new NOV-002 nonclinical data at the American Association for Cancer Research (AACR) Annual Meeting in April 2010. We also expect to initiate a Phase 2 hepatitis C trial shortly with our second compound NOV-205. Meanwhile, we intend to rebuild our pipeline through licensing or acquiring clinical-stage oncology compounds, utilizing our experienced and proven development team."

#### About Novelos Therapeutics, Inc.

Novelos Therapeutics, Inc. is a biopharmaceutical company commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis. Novelos is seeking to build a pipeline through licensing or acquiring clinical stage compounds or technologies for oncology indications. Our lead compound, NOV-002, has been administered to approximately 1,000 cancer patients in clinical trials and is in Phase 2 development for solid tumors in combination with chemotherapy. Novelos has a partnership with Mundipharma, an independent associated company of Purdue Pharma, to develop and commercialize NOV-002 in Europe and Asia (excluding China). Novelos' second compound, NOV-205, which has been administered to approximately 200 hepatitis patients in clinical trials, is in Phase 2 development for chronic hepatitis C non-responders. Both compounds have been partnered with Lee's Pharm in China. For additional information about Novelos please visit <a href="https://www.novelos.com">www.novelos.com</a>.

Novelos Therapeutics, Inc.
One Gateway Center, Suite 504
Newton, MA 02458

This news release contains forward-looking statements. Such statements are valid only as of today, and we disclaim any obligation to update this information. These statements 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.



### Contacts

Novelos Therapeutics, Inc.

#### **COMPANY**

Harry S. Palmin, 617-244-1616 x11 President and CEO hpalmin@novelos.com

or

#### **INVESTOR RELATIONS**

Stephen Lichaw, 201-240-3200 slichaw@novelos.com

