Novita Presents Additional Positive Data from Phase 2 Trial of NP-G2-044 in Patients with Advanced and Metastatic Solid Tumors at AACR IO Annual Meeting

New York, February 25, 2025 /PRNewswire/ -- Novita Pharmaceuticals, Inc. ("Novita"), a privately held, clinical-stage pharmaceutical company dedicated to developing novel cancer drugs through its proprietary fascin inhibitor technology, today announced additional results from its Phase 2 study (NCT05023486) evaluating NP-G2-044 in combination with SOC anti-PD-1 therapy in patients with advanced solid tumors resistant to prior anti-PD-1 therapy at the American Association for Cancer Research Immuno-oncology (AACR IO) Annual Meeting. The data was presented in a poster presentation titled "*Phase 2 Study of NP-G2-044, a Novel Fascin Inhibitor, in Combination with Anti-PD-1 Therapy in Patients with Solid Tumors Resistant to Prior Anti-PD-1 Therapy*." Findings indicate that NP-G2-044 provides a novel therapeutic opportunity when combined with ICIs.

"We are very pleased with the findings generated to date in our Phase 2 trial of NP-G2-044 both as a monotherapy and in combination with anti-PD-1 immune checkpoint inhibitors (ICIs) in ICI-resistant patients with advanced and metastatic solid tumors," said Jillian Zhang, Ph.D., President & Chief Scientific Officer of Novita. "The strong safety and durable efficacy we have observed with our first-in-class fascin inhibitor further support the simultaneous inhibition of metastasis and enhancement of cancer immunotherapy as a promising and innovative approach in cancer treatment with broad applications for many solid tumors. We look forward to sharing additional data from the Phase 2 expansion cohort of NP-G2-044 in combination with ICI in the second half of 2025."

Among the 45 patients treated with NP-G2-044 as of the last data cutoff (Oct. 2024), 80% had progressed on prior anti-PD-(L)1 therapies. The anti-PD-1 Combination RP2D for NP-G2-044 was 1600 mg QD with 4-week cycles. The primary endpoint was objective response rate (ORR), and secondary endpoints included progression-free survival (PFS), metastasis-free interval (MFI), overall survival (OS), safety, and tolerability.

Key highlights include:

- A Disease Control Rate of 76% (includes patients with Stable Disease and Objective Responses)
- An ORR of 21% (95% CL 9-38.9%) including 4 patients with Partial Response (PR) and 3 patients with Complete Responses (CR) including Pathologic Complete Response
- Results indicate durable responses and tumor control in a significant proportion of patients across at least seven cancer types, including cases converted from ICI-non-responsive to ICI-responsive.
- Long lasting objective responses have been observed.
- Notable outcomes include a CR in a cervical cancer patient, target lesion CR in an endometrial cancer patient, pathological CRs in a pancreatic cancer patient and a patient with gastroesophageal junction adenocarcinoma and PRs in cutaneous squamous cell carcinoma, non-small cell lung cancer, and cholangiocarcinoma.
- Seven patients are still on treatments, with the longest duration of 18+ months in an endometrial cancer patient and a patient with pancreatic cancer.

An amendment to the study is underway to open additional cohorts. These new cohorts aim to further evaluate the combination of NP-G2-044 with anti-PD-1 therapy across patient populations and solid tumor subtypes, providing a broader understanding of its therapeutic potential. Future analysis will also explore biomarkers for response prediction and mechanisms of resistance, guiding personalized approaches in treatment-resistant cancer. Novita is on track to begin enrollment in its pivotal Phase 3 study of NP-G2-044 + PLD in platinum resistant ovarian cancer in the third quarter of 2025.

About Novita's Pioneering Research in Fascin Inhibition

Cancer metastasis is the primary cause of over 90% of cancer-related deaths, yet there is currently no drug on the market specifically targeting metastasis. Furthermore, while Immuno-Oncology (IO) therapies, particularly immune checkpoint inhibitors, have made significant strides in cancer treatment, a large proportion of patients do not respond to existing IO treatments. Novita aims to address both of these critical medical needs by developing fascin inhibitors, which target a key protein involved in tumor cell motility and highly expressed in tumor cells and antigen-presenting cells within tumor tissues. The Company's lead asset, NP-G2-044, is a small-molecule fascin inhibitor that has demonstrated the ability to block metastasis in both preclinical and clinical studies. Additionally, when combined with immune checkpoint inhibitors, NP-G2-044 has shown potential to reinvigorate anti-tumor immune responses. Novita's multicenter Phase 2 clinical trial, titled "NP-G2-044 as Monotherapy and Combination Therapy in Patients with Advanced or Metastatic Solid Tumor Malignancies," is currently ongoing.

About Novita Pharmaceuticals, Inc.

Novita Pharmaceuticals, Inc. is a privately held, clinical-stage biopharmaceutical company focused on developing groundbreaking therapies using its proprietary fascin inhibitor technology to prevent and treat cancer metastasis while simultaneously enhancing anti-cancer immune responses. For more information, visit www.novita-pharm.com/

Cautionary Note Regarding Forward-Looking Statements

This press release contains certain forward-looking statements. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. These statements are based on a number of assumptions and estimates that are inherently subject to significant uncertainties and contingencies, many of which are beyond the Company's control, and respect future business decisions, which are subject to change. Among those factors that could cause actual results to differ materially from those described in the forward-looking statements are the risks associated with the Company's being a development stage company with uncertain revenue streams; uncertain results or outcomes during clinical trials; failure to raise necessary capital in the future; the loss of key personnel; competition from other larger, better-capitalized peers; the Company's reliance on incorrect assumptions regarding the market for its products, the costs of developing, manufacturing and marketing the Company's products, and the timing and receipt of regulatory approval for the Company's products; adverse economic conditions; and other risks. In light of the significant uncertainties inherent in the forward-looking statements, the inclusion of any such statement should not be regarded as a representation by Novita or any other person that the Company's objectives or plans will be achieved.

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