Novita Highlights Positive Data from Phase 2 Trial of NP-G2-044 in Patients with Advanced and Metastatic Solid Tumors at 2025 ASCO Annual Meeting

New York, May 22, 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 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The oral presentation, titled "*Durable responses in ICI-refractory or acquired resistance: Phase 2 study of NP-G2-044 combined with anti-PD-1 therapy*", further supports the potential therapeutic benefit of NP-G2-044 in combination with immune checkpoint inhibitors (ICIs) to block metastasis and enhance immune response.

"We are encouraged by the continued positive data from our Phase 2 trial of NP=G2-044, which highlight the therapeutic opportunity of our first-in-class fascin inhibitor for patients with advanced and metastatic solid tumors," said Jillian Zhang, Ph.D., President & Chief Scientific Officer of Novita. "Continued safety and durable efficacy findings across multiple tumor types speak to the impact of our novel therapy, as we see favorable response rates and no new metastases from more than half of patients. These data set the foundation for our Phase 3 study of NP-G2-044 + PLD in platinum resistant ovarian cancer, which we plan to start enrolling later this year."

Among the 45 patients treated with NP-G2-044 as of the most recent data cutoff (April 23, 2025), all had progressed on prior anti-PD-(L)1 therapies, with a median number of 2 prior lines, and with 20% of patients having at least 4 prior lines. 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% including three patients with Partial Response (PR) and four patients with Complete Responses (CR) including two Pathologic Complete Responses.
- 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 across multiple tumor types, with four patients in ongoing treatment, two of which show duration lasting more than 80 weeks in pancreatic cancer and endometrial cancer.
- 55% of all patients show no new metastases.
- Notable outcomes include continued 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, clinical CR in a cutaneous squamous cell carcinoma patient, and PRs in non-small cell lung cancer and cholangiocarcinoma.

- Increased T-cell infiltration and enhanced proliferation as well as expanded activated dendritic cells (DCs) in the tumor microenvironment were observed, supporting the therapeutic function of fascin inhibition and immune activation.

An amendment to the study is currently underway to open additional cohorts, which will aim to further evaluate the combination of NP-G2-044 with anti-PD-1 therapy across patient populations and solid tumor subtypes. Future analysis will also explore biomarkers for response prediction and mechanisms of resistance, guiding personalized approaches in treatment-resistant cancer. Novita plans to share additional data from the Phase 2 expansion cohort of NP-G2-044 in combination with ICI in the second half of 2025 with enrollment in its pivotal Phase 3 study of NP-G2-044 + PLD in platinum resistant ovarian cancer expected to begin 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

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