Novita Pharmaceuticals Announces FDA Orphan Drug Designation Granted to NP-G2-044 for the Treatment of Pancreatic Cancer

Designation encompasses treatment of pancreatic cancer, including use in combination with immune checkpoint inhibitors

New York, NY – January 12, 2026 /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 that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to its investigational small-molecule fascin inhibitor, NP-G2-044, for the treatment of pancreatic cancer. Pancreatic cancer is among the deadliest malignancies, with a five-year survival rate of approximately 12% and limited effective treatment options, particularly in advanced disease.

“FDA Orphan Drug Designation for our fascin inhibitor represents an important regulatory milestone for Novita and validates the Company’s scientific and clinical approach in the fight against pancreatic cancer, as it remains one of the most lethal solid tumors with limited therapeutic progress over decades,” said Stewart Campbell, Chief Executive Officer of Novita Pharmaceuticals. “Fascin inhibition offers a novel approach with the potential to enhance anti-tumor immune activity and improve outcomes for patients with this devastating disease, and we look forward to continuing advancement of NP-G2-044 to address the high unmet need.”

Orphan Drug Designation is granted to investigational therapies intended to treat rare diseases affecting fewer than 200,000 patients in the United States. The designation provides development incentives, including eligibility for tax credits on qualified clinical trial costs, exemption from certain FDA user fees, and the potential for seven years of market exclusivity upon regulatory approval.

The FDA’s Orphan Drug Designation was granted by the FDA’s Office of Orphan Products Development (OOPD) and includes treatment of pancreatic cancer in the setting of immune checkpoint inhibitor (ICI) therapy, which falls within the scope of the approved orphan indication. As noted by the FDA, orphan designation applies to the active moiety of the drug rather than a specific formulation, and eligibility for orphan drug exclusivity will ultimately depend on the approved indication and demonstration of clinical benefit relative to any approved therapies in the same indication.

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/.

Media Contact:
Argot Partners (media)
David Rosen
212.600.1902
David.Rosen@argotpartners.com

Investor Contact:
Argot Partners (investors)
Sam Martin
212.600.1902
novita@argotpartners.com