Nuvectis Pharma Reports Encouraging NXP800 Interim Data Supporting Ongoing Enrollment in Phase 1b Study in Patients with Platinum-Resistant ARID1a-Mutated Ovarian Cancer

- NXP800 demonstrated single agent activity
- New dosing schedule successfully minimized thrombocytopenia

Fort Lee, NJ, Nov. 14, 2024 (GLOBE NEWSWIRE) -- Nuvectis Pharma, Inc. (NASDAQ: NVCT), a clinical-stage biopharmaceutical company focused on the development of innovative precision medicines for the treatment of serious conditions of unmet medical need in oncology, today reported encouraging data from the Phase 1b study evaluating NXP800 in patients with platinum resistant ARID1a-mutated ovarian cancer. Platinum-resistant, ARID1a-mutated ovarian cancer is a serious condition that carries a poor prognosis with an estimated life expectancy of approximately one year from diagnosis.

The NXP800 development program in this disease was granted Fast Track Designation by the U.S. Food and Drug Administration ("FDA"), and NXP800 was granted Orphan Drug Designation by the FDA for the treatment of ARID1a deficient ovarian, fallopian tube and primary peritoneal cancers.

Phase 1B Update

Three dosing regimens have been evaluated to date in twelve patients (four patients were treated on a once per day dosing schedule, two with 75 mg/day and two with 50 mg/day. Subsequently, eight additional patients were treated with 50 mg/day on an intermittent dosing schedule of five days on / two days off, a dosing schedule implemented to mitigate thrombocytopenia). All patients enrolled into the study failed at least two prior lines of systemic chemotherapy, including at least one prior platinum-based chemotherapy regimen, and most had also failed treatment with bevacizumab.

In eleven efficacy-evaluable patients, antitumor activity was observed with best responses including one patient with an unconfirmed partial response and six patients with stable disease, including tumor shrinkage.

The Phase 1b interim data reported earlier this year included four patients evaluable for safety, of which three experienced Grade 4 thrombocytopenia. Subsequently, in the eight patients treated with NXP800 using the intermittent dosing schedule (50 mg/day, 5 days on / 2 days off), the highest grade of thrombocytopenia observed was Grade 2 (one patient). Other than thrombocytopenia, the most common treatment emergent adverse events included nausea, fatigue, vomiting, diarrhea and constipation, the majority of which being Grade 1-2.

Ron Bentsur, Chairman and Chief Executive Officer of Nuvectis, commented: "We continue to be encouraged by the early results from our Phase 1b study with NXP800. The antitumor activity observed despite patients' advanced disease and extensive pre-treatment, while controlling for thrombocytopenia, is promising. However, it is clear that we need to increase the dose intensity to drive more efficacy in the next set of patients. We are already enrolling patients into a cohort of up to 10-12 additional patients utilizing a regimen of 75 mg/day on an intermittent dosing schedule, which is expected to be the last cohort in this Phase 1b study. We believe that NXP800 is an active agent and that this higher dose intensity should provide for increased exposure that could enable us to reach our goal of demonstrating enhanced activity with acceptable overall tolerability. We expect to provide additional clinical data from the Phase 1b study in the

second quarter of 2025."

Mr. Bentsur concluded, "With the Phase 1b study advancing as described, we also expect to regain momentum in the ongoing Investigator-Initiated Study in cholangiocarcinoma, being conducted in collaboration with the Mayo Clinic. We believe that together with NXP900's continued advancement and significant development options of blockbuster potential, our pipeline positions us to deliver on our mission of developing novel treatments for serious conditions of unmet medical needs in oncology."

About the Phase 1b Study

The Phase 1b study is a multicenter, single arm, open-label clinical trial of NXP800 in patients with platinum-resistant, ARID1a-mutated ovarian cancer. The study is designed to examine the safety and preliminary efficacy of NXP800 in this target patient population.

The study is being conducted in the US and UK in collaboration with the GOG Foundation, Inc. and the European Network of Gynecological Oncological Trial Groups, recognized as the world's leading gynecology oncology clinical trials consortia.

About NXP800

NXP800 is an oral, small molecule, potentially first-in-class GCN2 kinase activator. The NXP800 development program in platinum-resistant, ARID1a-mutated ovarian cancer was granted Fast Track Designation by the FDA, and Orphan Drug Designation for the treatment of ARID1a-deficient ovarian, fallopian tube and primary peritoneal cancers. NXP800 is also being evaluated in an investigator-initiated study conducted in collaboration with the Mayo Clinic for the treatment of cholangiocarcinoma. The FDA has also granted NXP800 Orphan Drug Designation in this indication.

Nuvectis licensed exclusive world-wide rights to NXP800 from the Institute of Cancer Research in London, UK.

About Platinum-Resistant, ARID1a-Mutated Ovarian Carcinoma

ARID1a-mutated ovarian carcinoma is comprised almost exclusively of two histologies, ovarian clear cell carcinoma ("OCCC") and ovarian endometrioid carcinoma ("OEC"), each representing about 10% of the overall ovarian cancer cases in the U.S. with an annual incidence of approximately 2,200 patients per histology. Platinum resistant ovarian carcinoma is recognized as a serious condition of unmet medical need, given the lack of effective treatments and the poor patient prognosis in this setting, with median life expectancy estimated to be approximately one year upon diagnosis. It is estimated that approximately 66% of patients with OCCC and 40% of patients with OEC have the ARID1a-mutation.

About Nuvectis Pharma, Inc.

Nuvectis Pharma, Inc. is a biopharmaceutical company focused on the development of innovative precision medicines for the treatment of serious conditions of unmet medical need in oncology. The Company is currently developing two clinical-stage drug candidates, NXP800 and NXP900. NXP800 is an oral small molecule GCN2 activator currently in a Phase 1b clinical trial for the treatment for platinum resistant, ARID1a-mutated ovarian carcinoma and in an Investigator-sponsored clinical trial for the treatment of cholangiocarcinoma. NXP900 is an oral small molecule inhibitor of the SRC Family of Kinases (SFK), including SRC and YES1. NXP900 has a unique mechanism of action in that it inhibits both the catalytic and scaffolding functions of the SRC kinase thereby providing complete shutdown of the signaling pathway. NXP900 is currently in a Phase 1a dose escalation study.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties. All statements, other than statements of historical fact,

contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Nuvectis Pharma, Inc.'s current expectations, including safety and efficacy data generated to date for NXP800 and NXP900, estimates, and projections about future events and trends that we believe may affect our business, financial condition, results of operations, prospects, business strategy, and financial needs. The outcome of the events described in these forward-looking statements are subject to inherent uncertainties, risks, assumptions, market and other conditions, and other factors that are difficult to predict and include statements and data regarding the preclinical studies for NXP800 and NXP900, and the Phase 1a data for NXP800 and the NXP900 Phase 1a study to date, as well as the clinical expectations for the ongoing NXP800 Phase 1b study in platinum-resistant, ARID1a-mutated ovarian carcinoma, including the potential ability of a higher dose intensity going forward in the NXP800 Phase 1b study to generate satisfactory safety and efficacy results, statements regarding NXP800's potential ability to become a therapeutic option for the treatment of platinum-resistant, ARID1a-mutated ovarian carcinoma, cholangiocarcinoma, and potentially other cancer indications, and the timing for completion of the clinical trials, including the ongoing NXP800 investigator-initiated study in cholangiocarcinoma and statements regarding NXP900's therapeutic potential. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are subject to market and other conditions and described more fully in the section titled "Risk Factors" in our 3Q 2024 Form 10-Q and our other public filings with the Securities and Exchange Commission ("SEC"). However, these risks are not exhaustive and new risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this press release or other filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date of this press release. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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