

Nanopharmaceutics Announces End of Patient Recruitment for NCI Phase II Study with Triapine for Neuroendocrine Tumors

Nanopharmaceutics Inc. Announces End of Patient Recruitment of NCI Phase II Clinical Study with Lutetium Lu 177 Dotatate +/- Triapine for Neuroendocrine Tumors

ALACHUA, FL, UNITED STATES, July 18, 2025 /EINPresswire.com/ -- ALACHUA, Fla., July 18, 2025 -- Nanopharmaceutics, Inc., a clinical-stage pharmaceutical development company, today announced completion of patient enrollment in the 94 patient Phase 2 clinical study "A Phase II Randomized Control Trial of Triapine Plus Lutetium Lu 177 Dotatate Versus Lutetium Lu 177 Dotatate Alone for Well-Differentiated Somatostatin Receptor-Positive Neuroendocrine Tumors". The study (NCI protocol 10558, ClinicalTrials.gov Identifier: NCT05724108) is sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, conducted by NCI funded Experimental Therapeutics Clinical Trials Network (ETCTN) with the Ohio State University Comprehensive Cancer Center as the lead institution. The randomized phase 2 trial is evaluating (PRIMARY OBJECTIVE) the overall response rate (ORR) by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 of combination Triapine® + lutetium Lu 177 dotatate (treatment arm 1) versus standard of care lutetium Lu 177 dotatate alone (treatment arm 2) and (SECONDARY OBJECTIVE) to evaluate progression-free survival (PFS) between the two treatment arms (combination arm 1 versus standard of care arm 2).

This phase II trial compares the effect of adding Triapine® to lutetium Lu 177 dotatate versus lutetium Lu 177 dotatate alone (standard therapy) in shrinking tumors or slowing tumor growth in patients with neuroendocrine tumors that have spread from where they first started (primary site) to other places in the body (metastatic). Triapine® may stop the growth of tumor cells by blocking some of the enzymes needed for deoxyribonucleic acid synthesis and cell growth. Lutetium Lu 177 dotatate is a radioactive drug. It binds to a protein called somatostatin receptor, which is found on some neuroendocrine tumor cells. Lutetium Lu 177 dotatate builds up in these cells and gives off radiation that may kill them. It is a type of radioconjugate and a type of somatostatin analog. This study tests whether adding Triapine® improves shrinking tumors or slowing tumor growth in patients with metastatic neuroendocrine tumors than the standard therapy of lutetium Lu 177 dotatate alone. 94 patients were enrolled in the study, which was performed under a Cooperative Research and Development Agreement (CRADA) between NCI and Nanopharmaceutics. The phase II trial passed the pre-planned interim safety review and interim futility assessment and is awaiting primary endpoint maturity.

About Triapine®

Triapine® is a synthetic heterocyclic carboxaldehyde thiosemicarbazone with potential antineoplastic activity being studied in the treatment of cancer. It is a type of ribonucleotide reductase inhibitor. Also called 3-aminopyridine-2-carboxaldehyde thiosemicarbazone and 3-AP, Triapine® inhibits the enzyme ribonucleotide reductase, resulting in the inhibition of the conversion of ribonucleoside diphosphates to deoxyribonucleotides necessary for DNA synthesis.

About Nanopharmaceutics, Inc.

Nanopharmaceutics, Inc. is a clinical-stage specialty pharmaceutical company developing oral, topical, and injectable products for cancer, central nervous system (CNS) disorders, and infectious diseases. Nanopharmaceutics is focused on formulation development aimed at improving drug absorption and stability. Nanopharmaceutics is a subsidiary of TRON Group Inc. (OTC:TGRP).

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