NETRIS Pharma Announces FDA Orphan Drug Designation (ODD) for NP137 in Pancreatic Cancer Treatment

LYON, FRANCE, AND GENEVA, SWITZERLAND, November 21, 2024 /EINPresswire.com/ -- NETRIS Pharma, a clinical-stage biopharmaceutical company pioneering therapies to overcome resistance in oncology, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to NP137 for the treatment of pancreatic cancer. NP137 is being developed to block metastases and prevent treatment resistance when used in combination with chemotherapy or immunotherapy.

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>
> *Patrick Mehlen, CEO*

Pancreatic cancer remains a devastating disease, with over 66,000 new cases diagnosed annually in the U.S. alone. The five-year survival rate is less than 5%, underscoring the urgent need for novel therapeutic approaches.

"The FDA's decision to grant ODD for NP137 highlights the critical need for innovative treatments in Pancreatic Cancer, including those designed for combination with current standards of care such as FOLFIRINOX" said Patrick Mehlen, Founder and Chief Executive Officer of NETRIS Pharma. "Further to the publication of NP137's mode of action in two back-to-back Nature® papers, this designation supports our ambition in addressing some of the most challenging cancers," he added.

NP137 is currently being investigated in the LAP-NET1 study (NCT05546853), in combination with mFOLFIRINOX as a first-line treatment for locally advanced Pancreatic Ductal AdenoCarcinoma (PDAC). "Given the upregulation of NETRIN-1 in pancreatic cancer and its role in promoting epithelial-to-mesenchymal transition (EMT), a major driver of metastasis and of resistance to chemotherapy, we believe that NP137 can significantly improve treatment outcome," explained Patrick Mehlen. "Very encouraging interim results from the first 20 patients in the LAP-NET1 trial strongly validate the potential of NP137, and we are actively preparing the next steps in NETRIS

Pharma's development."

Gael Roth, GI Oncologist at Grenoble-Alpes Hospital, France and Principal Investigator for LAP-NET1, commented: "FOLFIRINOX is the most widely used FDA-approved chemotherapy for pancreatic cancer and the LAPNet1 study did not show any unexpected additional toxicity of the combination with NP137. Patient enrollment in this study has been very active and I look forward to the primary analysis of the full 43 patients enrolled in LAP-NET1 in the first quarter of 2025."

The FDA grants Orphan Drug Designation to drugs or biologics that address rare diseases affecting fewer than 200,000 people in the U.S. This designation qualifies NETRIS Pharma for incentives, including tax credits for clinical trials, waiver of user fees, and potential seven years of market exclusivity upon approval of NP137 for all pancreatic cancer indications.

About NP137
NP137 is a humanized monoclonal antibody of isotype IgG1 directed against netrin-1. Netrin-1 is overexpressed in a large number of human cancers, preventing cells from apoptosis. Expression of netrin-1 often correlates with disease severity and no therapy has ever been tested against this new pathway. Preclinical studies show NP137 has an anti-cancer effect as a monotherapy as well as synergistic effects in combination with chemotherapy or immune checkpoint inhibitors. After confirmation of the excellent safety profile in human, NETRIS Pharma is currently actively recruiting in four clinical trials: GyNET trial (NCT04652076), ImmunoNET (NCT05605496) and Liver-NET1 (NCT05546879) and LAP-NET1 (NCT05546853).

About NETRIS Pharma
NETRIS Pharma is a clinical-stage biopharmaceutical company developing innovative therapeutic molecules targeting NETRIN-1, a protein aberrantly expressed in cancer cells that triggers EMT, one of the main cause of resistance to oncology therapies. NETRIN-1 has also been reported in other proliferation disorders such as endometriosis and fibrosis. Our lead product, NP137, is the most advanced product candidate targeting NETRIN-1 and its mode-of-action has been published in Nature® in 2023.
Further information can be found at: https://www.netrispharma.com.

Contact:
NETRIS Pharma
Christophe GUICHARD, CFO and IR,
christopheguichard@netrispharma.com

Christophe GUICHARD
NETRIS Pharma
+33 4 78 78 29 53
email us here