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PRESS RELEASE

NH TherAguix Announces the completion of Phase I Recruitment for the Pancreas Cohort and the entry into Phase II in the NANOSMART phase Ib/II trial.

- **Key clinical milestone showcasing the potential of AGuIX®, a next-generation nanodrug developed by NH TherAguix, to improve tumor targeting and augment efficacy when combined with radiotherapy in solid tumors.**
- **NANOSMART is a phase Ib/II clinical trial investigating the safety and efficacy of the combination of AGuIX® intravenous injections with stereotactic magnetic resonance (MR)-guided adaptive radiation therapy for the treatment of locally advanced/unresectable pancreatic ductal adenocarcinoma (LAPC) and of centrally located non-small cell lung cancer lesions.**
- **The Principal Investigator, Jonathan Leeman, MD, at Brigham & Women's Hospital and The Dana-Farber Cancer Institute, announce the transition to the Phase II randomized part of the study in the cohort of patient with pancreatic tumors.**

Paris, France, July 1st, 2024 – NH TherAguix (NHT), a phase II clinical-stage biotechnology company specializing in the development of novel nanomedicine solutions for precision radiotherapy in oncology, today announced the transition to the Phase II randomized part of the NANOSMART study in the cohort of patients with pancreatic tumors. The NANOSMART study, titled "**An adaptive phase I–II trial of AGuIX® gadolinium-based nanoparticles with stereotactic magnetic resonance-guided adaptive radiation therapy (SMART) for locally advanced unresectable pancreatic ductal adenocarcinoma and centrally located lung tumors,**" is currently ongoing to assess safety, biodistribution and radio-enhancement efficacy of the combination of AGuIX® intravenous injections.

AGuIX®: A Nanodrug Capable of Improving the Precision and Effectiveness of Radiotherapy

The culmination of over a decade of research, AGuIX® nanoparticles are designed to meet the critical medical need for more effective cancer treatments, including pancreatic cancer. These gadolinium-based nanoparticles enhance MRI contrast, allowing for precise tumor visualization, and significantly amplify the radiation dose delivered to tumor tissues, thereby improving the efficacy of radiotherapy.

NANOSMART: A Monocentric, Randomized, Open-Label Phase Ib/II Trial Conducted with the Dana-Farber Cancer Institute/Brigham & Women's Hospital Team

The aim of the dose escalation Phase I was to determine the recommended dose of the experimental drug to be evaluated in Phase II. Two dose levels of AGuIX® (75mg/kg and 100mg/kg) have been tested on twenty patients treated in the pancreas cohort during Phase I. These patients with locally advanced unresectable pancreatic ductal adenocarcinoma have received two injections of AGuIX® in combination with SMART (40 Gy in 5 fractions of 8 Gy).

AGuIX® injections were well-tolerated. Additionally, MRI analysis has confirmed that AGuIX® nanoparticles selectively accumulated in pancreatic tumors.

A good safety profile of AGuIX® in combination with SMART was confirmed.

“The transition to the Phase II randomized stage of the study in the cohort of patients with pancreatic cancer was approved by the institutional review board and the FDA at the recommended dose of AGuIX at 100mg/kg,” said **Dr Jonathan Leeman, the study P.I., from Brigham & Women’s Hospital and The Dana-Farber Cancer Institute.**

The Phase II part of NANOSMART study will be randomized within two arms: an experimental arm in which patients will be treated with AGuIX® at a dose of 100 mg/kg in combination with SMART (10 patients), and a control arm in which patients will be treated with SMART alone (20 patients).

The primary endpoint of this Phase II is local control at 12 months. Secondary endpoints include progression-free survival, overall response rate, disease-specific survival, quality of life and overall survival.

Dr. Olivier de Beaumont, CMO of NH TherAguix, emphasized the significance of this step: "AGuIX® Orphan Drug Designation was already granted by FDA and EMA for pancreatic tumors in 2021, and we are very happy to be able to continue the evaluation of AGuIX® in combination with SMART after confirmation of the good safety profile and biodistribution in patients with pancreatic tumors. I would like to thank Dr. Jonathan Leeman very much for his strong commitment to enrolling patients in the two cohorts (locally advanced/unresectable pancreatic ductal adenocarcinoma (LAPC) and centrally located non-small cell lung cancer lesions.”

Vincent Carrère, CEO of NH TherAguix, commented: "We are thrilled to announce this important next step of transition to the NANOSMART Phase II randomized part in pancreatic tumors. I would like to thank Dr Jonathan Leeman and the Dana-Farber Cancer Institute/Brigham & Women’s Hospital team for this remarkable clinical and translational work. It highlights the transformative potential of AGuIX® in enhancing radiotherapy for pancreatic cancer patients. This promising next step reinforces our commitment to advancing innovative cancer treatments and improving patient outcomes in difficult-to-treat indications."

About NH TherAguix: www.nhtheraguix.com

NH TherAguix is a late-stage biotech company developing AGuIX® to treat tumors and metastases in patients undergoing radiotherapy. It is estimated that approximately 60% of cancer patients receive radiotherapy. AGuIX® is currently being assessed in multiple Phase II randomized trials across various cancer types, including brain metastases, glioblastoma, and pancreatic and lung cancers.

To date, over 190 patients have been treated with AGuIX®. This innovation is protected by 18 patent families and has been extensively tested in various preclinical models, with results published in more than 80 high-impact publications.

NH TherAguix was established in 2015 following 10 years of academic research that led to the invention of AGuIX® and the discovery of its radiosensitizing effect. The company has raised approximately €40m of funds, including a €13m Series A in 2019 led by Bpifrance with Arbevel, Omnes, and Supernova.

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