

## PRESS RELEASE

# NH TherAguix announces continuation of the Phase II NANOBRAINMETS trial in the treatment of brain metastases after completion of a futility analysis

- **Validation by the Data Safety and Monitoring Board (DSMB) for the continuation of the study after the futility analysis performed on 50% of the total patient accrual.**
- **No serious adverse events related to AGuIX<sup>®</sup> have been reported to compromise the benefit risk profile of AGuIX.**
- **An interim efficacy analysis of AGuIX<sup>®</sup> in NANOBRAINMETS trial is expected by the end of 2024.**
- **NANOBRAINMETS is a Phase II clinical trial, conducted in collaboration with the Dana Farber Cancer Institute, evaluating AGuIX<sup>®</sup> in patients with brain metastases in combination with stereotactic radiotherapy<sup>1</sup>.**

**Paris, France, September 03<sup>rd</sup>, 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 that the Data Safety and Monitoring Board (DSMB) has validated the continuation of the Phase II trial, NANOBRAINMETS, managed by the Dana Farber Cancer Institute, following the futility analysis scheduled after the enrollment and follow up of 50% of patients in the study.

Ongoing evaluation of the study has revealed no serious adverse events related to the administration of AGuIX<sup>®</sup>, highlighting the very favorable safety profile of this drug candidate. Developed by NH TherAguix, AGuIX<sup>®</sup> is designed to improve tumor targeting and increase radiobiological damage to tumor tissue locally, thanks to its radiation signal amplification capabilities.

***96 patients have been randomized up to date on the 134 scheduled in the study's protocol.***

NANOBRAINMETS is a randomized, double-blind Phase II trial evaluating AGuIX<sup>®</sup> in combination with stereotactic radiotherapy in patients with brain metastases, compared with a control arm using stereotactic radiotherapy alone. **Next interim analysis is currently expected by the end of this year to assess the clinical efficacy of AGuIX<sup>®</sup>.**

**Dr. Ayal Aizer, MD, MHS, Director of the Central Nervous System Radiation Oncology Division at the Brigham and Women's Hospital / Dana-Farber Cancer Institute, principal investigator of the NANOBRAINMETS study said:** *"We are very pleased to continue this cutting-edge clinical trial, which evaluates a promising new treatment for patients suffering from brain metastases. This study could*

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<sup>1</sup> Stereotactic radiotherapy is a technique enabling the delivery of high-dose radiation to a target volume with very tight margins.

*lead to the development of a new standard of treatment for these devastating cancers, addressing a significant medical need today.”*

**Dr. Olivier de Beaumont, CMO of NH TherAguix said:** “We sincerely thank Dr. Aizer and the teams at the Dana-Farber Cancer Institute for constant and fruitful collaboration of more than 10 years of research with NHT team”.

**Vincent Carrère, CEO of NH TherAguix, added:** “This first positive step paves the way for the major next inflexion point expected in the second half of the year regarding the interim efficacy analysis of AGuIX<sup>®</sup>. The Phase II final results expected by Q2-Q3 2026 will be decisive for the further clinical development of AGuIX<sup>®</sup> and its commercial approval for treating these cancers with high medical need.”

**About NH TherAguix:** [www.nhtheraguix.com](http://www.nhtheraguix.com)

NH TherAguix is a Phase 2 biotech company developing AGuIX<sup>®</sup>, an innovative nano drug to treat tumors and metastases in patients undergoing radiotherapy. It is estimated that approximately 60% of cancer patients receive radiotherapy.

AGuIX<sup>®</sup> concentrates a high number of gadolinium atoms (~15) in an ultrasmall size object (~5 nanometers). Its pharmacological properties and its mode of action by bio-distribution allow it to enhance the precision and effectiveness of the radiotherapy directly in the heart of tumours and confer it a pan-cancer potential.

AGuIX<sup>®</sup> is currently being evaluated in multiple Phase II randomized trials across various cancer types:

- in brain metastases using either whole brain radiation therapy (NANORAD2, CHUGA, Grenoble, France) or stereo-radiosurgery (NANOBRAINMETs, Dana Farber Brigham Cancer Center, Boston, USA),
- in glioblastoma (NANOGBM, multicentric, Clermont Ferrand, France),
- in pancreatic and lung cancers (NANOSMART, Dana Farber Brigham Cancer Center, Boston, USA).

To date, over 200 patients have been treated with AGuIX<sup>®</sup> with an excellent safety profile and promising preliminary clinical results.

The innovation and technology behind the development of AGuIX<sup>®</sup> are protected by 18 patent families and have been extensively tested in various preclinical models, with results published in more than 80 high-impact, peer reviewed scientific publications.

#### Contact

NH TherAguix  
Vincent Carrère  
[mail](mailto:vincent.carrere@nhtheraguix.com)

#### Medias Contact

NewCap  
Arthur Rouillé  
[arouille@newcap.fr](mailto:arouille@newcap.fr) - +33 (0)1 44 71 00 15