

## PRESS RELEASE

# Nature's Scientific Reports publishes an article describing the quantification of novel radio-enhancer AGuIX<sup>®</sup> developed in brain metastases

- **Confirmation, consistently with already published<sup>1</sup> observations, of AGuIX<sup>®</sup> ability to act as a biomarker in clinical studies designed to assess its efficacy in the treatment of brain metastases, following intravenous injection**
- **Presentation of a method for quantifying and monitoring AGuIX<sup>®</sup> concentration by MRI after tumor targeting, paving the way for personalized radiotherapy by combining the diagnostic and therapeutic properties of AGuIX<sup>®</sup>**
- **Publication of translational scientific results from the NANOBRAINMETS Phase 2 clinical trial currently underway in the United States<sup>2</sup>, designed to demonstrate the therapeutic efficacy of AGuIX<sup>®</sup> in combination with standard radiotherapy treatments**

**Paris, France, June 10, 2024 – NH TherAguix (NHT)**, a phase II clinical-stage biotechnology company specializing in the development of novel nanomedicine solutions applicable to precision radiotherapy in oncology, today announced the publication in the peer-reviewed journal Scientific Reports, part of the Nature group, of an article describing a method for quantifying its next-generation radio-enhancer, AGuIX<sup>®</sup>, after tumor targeting. The article highlights the MRI biomarker properties of AGuIX<sup>®</sup> in addition to its radio-enhancing properties when combined with radiotherapy.

The article, entitled **“Quantifying gadolinium-based nanoparticle uptake distributions in brain metastases via magnetic resonance imaging”**, can be found on the Scientific Reports website: [Link](#).

AGuIX<sup>®</sup> nanoparticles offer a breakthrough in radiotherapy, addressing a key challenge by increasing efficacy while preserving surrounding healthy organs. Prior to treatment, AGuIX<sup>®</sup> serves as a biomarker visible on MRI, allowing for dose customization and image-guided irradiation to precisely target tumors and optimize therapy delivery. With its gadolinium-based structure, AGuIX<sup>®</sup> provides strong contrast imaging properties, while its capacity to amplify X-ray doses at the tumor site further enhances radiotherapy effectiveness.

The recently published article in Scientific Reports highlights AGuIX<sup>®</sup>'s potential as a biomarker in a study involving 23 patients with brain metastases. Each patient received either a 100 mg/kg intravenous dose of AGuIX<sup>®</sup> or a placebo, with subsequent biodistribution and quantification analyses conducted. This investigation is part of the ongoing randomized Phase II NANOBRAINMETS trial at the

<sup>1</sup> Verry C et al, 2020/2021

<sup>2</sup> Collaboration with the Dana Farber Brigham Cancer Center, Boston, USA. Principal investigator: Dr Ayal Aizer

Dana Farber Brigham Cancer Centre in Boston, USA. The trial aims to evaluate the efficacy of AGuIX<sup>®</sup> combined with stereotactic radiotherapy compared to stereotactic radiotherapy alone in patients with brain metastases. Quantification of AGuIX<sup>®</sup> on MRI images revealed that patients who received AGuIX<sup>®</sup> had nanoparticle concentrations in their brain metastases ranging from 0.012 to 0.17 mg/ml, with a mean concentration of 0.055 mg/ml. Patients receiving placebo showed no significant absorption in their brain metastases. These results confirm AGuIX<sup>®</sup> ability to infiltrate brain tumors in significant quantities.

Additionally, these data indicate that AGuIX<sup>®</sup> uptake by brain metastases was 35% higher than data from the Phase I NANORAD-1 trial previously conducted by NH TherAguix on 15 patients. In this trial, only 3 of the 15 patients had received the highest dose of 100 mg/kg, confirming a dose effect.

*"We are very pleased that our collaboration with the Dana Farber teams is regularly expanding and confirming the clinical evidence data for AGuIX<sup>®</sup> in the best possible conditions," said Olivier de Beaumont, CMO of NH TherAguix. "This publication is an acknowledgement of the research efforts made by the Dana Farber Cancer Institute teams, in collaboration with NHT teams, for the clinical development of our innovative nanomedicine. I would like to thank the Dana Farber Cancer Institute teams for the confidence they have shown in our project from the outset, as well as for their collaborative spirit, enabling us to enrich our knowledge of AGuIX<sup>®</sup>."*

The AGuIX<sup>®</sup> radio-enhancer is currently being evaluated in four Phase II trials in several types of solid tumors, in combination with radiotherapy. Three of these studies are expected to produce significant results by the end of 2024.

Although radiotherapy has experienced significant advancements in recent years, numerous challenges persist in providing patients with the most effective and precise treatment available. This publication, alongside our recent Fast Track designation by the US FDA, underscores the potential of our next-generation radio-enhancer for treating brain metastases and glioblastoma, among the most lethal cancers globally. We firmly believe that the forthcoming results from our clinical trials, anticipated later this year, will chart a new course in therapeutic approaches for these medically urgent conditions," **concluded Vincent Carrère, CEO of NHT.**

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

NH TherAguix is a late-stage biotech company developing AGuIX<sup>®</sup> to treat tumours and metastases in patients treated by radiotherapy. It is estimated that c.60% of cancer patients undergo radiotherapy treatment today.

AGuIX<sup>®</sup> is currently assessed in 4 Phase II randomized trials 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) as well as in pancreatic and lung cancers (NANOSMART, Dana Farber Brigham Cancer Center, Boston, USA).

Results of the First in Human Phase I trial in brain metastases (NANORAD1, CHUGA, Grenoble, France) and advanced cervix cancer (NANOCOL, IGR, Paris, France) have confirmed AGuIX<sup>®</sup> safety and efficacy profile (Verry et al, Science Advances 2020, Verry et al. Radiotherapy & Oncology, 2021; Chargari et al, 2024 ACS Nano *in press*). To date more than 185 patients have been treated with AGuIX<sup>®</sup>.

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AGuIX® has been extensively tested in various preclinical models and the results published more than 80 times in high impact publications. This innovation is protected by 18 patent families.

NH TherAguix was established in 2015 after 10 years of academic research in the founders' laboratories that led to the invention of AGuIX® and the discovery of its radiosensitizing effect.

Altogether, NH TherAguix raised around €40m of dilutive and non-dilutive funds, including a €13m A series in 2019, led by Bpifrance with Arbevel, Omnes and Supernova.

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