NH TherAguix SA
19 chemin du vieux chêne
38240 Meylan - FRANCE

PRESS RELEASE

NH TherAguix receives FDA Fast Track designation for AGuIX®, its novel radio-enhancer in the treatment of malignant gliomas, and provides an update on its developments and prospects

- **Key regulatory milestone confirming the interest of the US authorities in AGuIX®, a next-generation nanodrug developed by NH TherAguix to improve tumor targeting and increase local radiobiological damage in tumor tissue by amplifying irradiation signal**

- **Continuation of Phase II clinical developments in brain tumors and glioblastoma with major clinical milestones expected in the second half of 2024**

Paris, France, May 30, 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 that its lead drug candidate, AGuIX®, has received Fast Track designation from the U.S. Food and Drug Administration (FDA) as a next-generation radio-enhancer for the treatment of malignant gliomas, and in particular glioblastoma (GBM), the most common and deadliest brain cancer globally.

A nanodrug capable of improving the precision and effectiveness of radiotherapy without damaging surrounding tissues

The result of over 10 years of research, AGuIX® is a nanodrug designed to meet the growing medical need in brain cancer, by significantly improving the efficacy and precision of radiotherapy directly within tumors.

Its structure mostly made of gadolinium provides it with strong contrast imaging properties, coupled with the potential to indirectly increase the delivered X ray dose. AGuIX® thus enables precise tumor delineation via MRI and can significantly improve radiotherapy efficacy. AGuIX® also boasts an excellent safety profile, as demonstrated by the results of the first *In Human* Phase Ib clinical trial NANORAD-1.

This new designation marks an important regulatory milestone for NH TherAguix, paving the way for accelerated development of its lead drug candidate, and is in line with the deployment of the company's new development strategy, following the recent appointment of Vincent Carrère as CEO.

Vincent Carrère, a pharmaceutical industry expert, appointed as CEO to steer the late-stage clinical development of AGuIX®

Last September, Vincent joined NH TherAguix to lead the final steps of AGuIX® clinical developments through registration trials, until expected market approval. Formerly Vice President - Head of the Northern and Central Europe Region at Ipsen, he brings over 15 years of experience in the

pharmaceutical and biotech industry. His deep knowledge of the processes and final stages of drug development and commercial launch will be instrumental in finalizing the upcoming developments of AGuIX®.

"We are delighted to have received this FDA Fast Track designation for AGuIX® in the treatment of malignant glioma. It demonstrates the strong interest of the US regulatory authorities in our next-generation radio-enhancer. We are convinced that AGuIX® holds great potential to offer an effective clinical and therapeutic response to patients suffering from these deadly cancers, for whom existing treatments remain largely insufficient. 2024 should be a major turning point in the development of our promising nano-drug, and we look forward to sharing the first results from our clinical trials later this year," **said Vincent Carrère, CEO of NH TherAguix.**

Major clinical inflection points expected in H2 2024

AGuIX® is currently being evaluated in four Phase II clinical trials, out of which three should provide major inflection points before the end of 2024:

- The **Phase II NANORAD 2 study**, conducted by Grenoble University Hospital (p.i. Pr. C. Verry) on 100 patients with multiple brain metastases, is evaluating AGuIX® in combination with whole brain radiotherapy[1]. Recruitment has been finalized and results of the interim efficacy analysis are expected by the end of 2024 at the latest.

- The **Phase II NANOBRAINMETS** trial, conducted in collaboration with the Dana Farber Cancer Institute (p.i. Dr. A. Aizer), the world's leading institute for adult and pediatric cancer research and treatment, is evaluating AGuIX® in 134 patients with brain metastases in combination with stereotactic radiotherapy[2]. A futility analysis (50% of patients enrolled) is scheduled for August 2024 to assess the first potential effects of the treatment on patients. Validation of the continuation of the study would underline the strong therapeutic potential of AGuIX® in the treatment of these patients. Initial results from an interim efficacy analysis are then expected in November 2024.

- The **Phase I/II NANOGBM trial,** conducted by Clermont Ferrand Centre Jean Perrin (p.i. Dr. J. Biau), is evaluating AGuIX® in the treatment of glioblastoma in 62 patients. Results from the interim efficacy analysis are expected by the end of 2024.

"Glioblastoma are the most common type of malignant primary brain tumor and account for most deaths among patient with primary tumors. Although there has been progresses in understanding the biology of these tumors, the unmeet therapeutic need remains very important. This Fast Track designation will facilitate NH TherAguix more frequent interactions with the FDA as well as accelerated approval and priority review in glioblastoma indications. This program will be led in parallel to our ongoing clinical development program in brain metastases, where preliminary signal of efficacy of AGuIX® has already been detected," **concluded Olivier de Beaumont, CMO of NH TherAguix.**

[1] Radiotherapy method that irradiates all tumours in the brain at once.
[2] High-precision radiotherapy that enables very small volumes of the patient's body to be irradiated at high doses, focusing radiotherapy on very precise areas.

About NH TherAguix : www.nhTherAguix.com

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

AGuIX® 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® 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®.

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.

Media contacts:

NH TherAguix
NewCap - Arthur Rouillé
arouille@newcap.fr
+33 (0)1 44 71 00 15