



NH TherAguix and Jean PERRIN Cancer Centre in Clermont-Ferrand announce the completion of phase I recruitment and the entry into Phase II for the Nano-GBM phase I/II trial in glioblastoma with the two first patients included.

Newsletter

Meylan (France) and Clermont-Ferrand (France), September 19, 2023

NH TherAguix (“NHT”), a research-based biotech company specialized in the development of innovative nanomedicines for the treatment of cancer by radiotherapy, and Jean PERRIN Cancer Center in Clermont-Ferrand announce the completion of phase I recruitment and the entry into Phase II for the Nano-GBM phase I/II trial in newly diagnosed glioblastoma, sponsored by Jean PERRIN Cancer Center and led by Pr Julian Biau, radiation oncologist.

This phase I/II clinical trial investigates the tolerance and efficacy of the combination of AGuIX[®] intravenous injections with radiotherapy plus concomitant temozolomide in the treatment of newly diagnosed glioblastoma.

Nano-GBM is a multicentric, randomized, open-label and non-comparative Phase I/II trial. The aim of the dose escalation phase I was to determine the recommended dose of experimental drug to be evaluated for the phase II. 3 dose levels of AGuIX[®] (50mg/kg, 75mg/kg and 100mg/kg) have been tested on eight patients treated in Phase I. These patients with unresected or partially resected glioblastoma have received four injections of AGuIX[®] in combination with temozolomide (75 mg/m²/day) and radiotherapy (60 Gy in 30 fractions of 2 Gy), followed by adjuvant temozolomide according to Stupp protocol, as the standard of care. AGuIX[®] injections were well-tolerated. In addition, MRI analysis has confirmed that AGuIX[®] nanoparticles selectively accumulated in glioblastoma. The Data Safety Monitoring Board, an independent group of experts external to the trial, has confirmed the safety profile of AGuIX[®] in combination with chemo-radiotherapy for the

treatment of glioblastoma patients, has validated the recommended dose chosen as well as the continuation of the trial into Phase II.

Pr. Julian Biau stated: "We are happy to have successfully completed the phase I at Jean PERRIN Cancer Center. Based on a favorable safety profile of AGuIX® in combination with Stupp protocol, we are encouraged to pursue assessment of this nanoparticle efficacy within the phase II of this innovative clinical trial, in collaboration with other investigator centers".

Dr. Olivier de Beaumont, CMO of NHT said: "After first hints of efficacy in brain metastases indication, NHT is pursuing further the clinical assessment of AGuIX® in neuro-oncology. Based on a robust scientific package demonstrating efficacy of AGuIX® in rodents with glioblastoma, this phase I/II clinical trial was designed with the objective to demonstrate the safety and efficacy of AGuIX® in patients with glioblastoma de novo. With the completion of the phase I of the Nano-GBM study, we are confirming the good tolerance of AGuIX® administered at 100mg/kg via intravenous infusions and we are extremely proud to enter the phase II randomized part of the study with the objective to show a patient clinical benefit in combination with Stupp protocol as standard of care".

This phase II study will be randomized with two arms: an experimental arm in which patients will be treated with AGuIX® at a dose of 100 mg/kg in combination with radio-chemotherapy (40 patients), and a control arm in which patients will be treated with radio-chemotherapy alone (20 patients). To date, the two first patients of the phase II have been included in the control arm.

The primary endpoint of this phase II study is progression-free survival at 6 months. Secondary endpoints include AGuIX® distribution in tumors, progression-free survival, overall survival, overall objective response rate and the safety profile of AGuIX® in combination with radiotherapy and temozolomide.

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 stereoradiosurgery (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) have confirmed AGuIX® safety and efficacy profile (Verry et al, Science Advances 2020, Verry et al. Radiotherapy & Oncology, 2021).

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.

About Jean PERRIN Cancer Centre in Clermont-Ferrand (www.cjp.fr) :

The Centre Jean PERRIN is one of the 18 French comprehensive cancer centers within UNICANCER, the only French hospital network 100% dedicated to the fight against cancer. Bringing together almost 900 professionals, the Center carries out a triple mission of public hospital service for the benefit of 33,000 patients a year:

- CARE: Coordinated, multidisciplinary cancer care, guaranteeing access to secondary and referral care for the local population,
- RESEARCH: specialized cancer research at the cutting edge of knowledge and innovation,
- EDUCATION: teaching, training and prevention missions.

The Centre Jean PERRIN advocates equal access to care, offering all the examinations, treatments and follow-up necessary for high-quality cancer care to all patients on a single site, with no extra charges.

The hospital also holds authorizations for a wider range of care activities, including adult intensive care and thoracic surgery, and has the only university hospital nuclear medicine service in Auvergne.

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