



PHOST'IN THERAPEUTICS ANNOUNCES APPROVAL OF FRENCH AND ITALIAN HEALTH AGENCIES FOR A FIRST EUROPEAN CLINICAL TRIAL APPLICATION IN PATIENTS WITH ADVANCED SOLID TUMORS, IN COLLABORATION WITH GIANNI BONADONNA FOUNDATION

Montpellier, France – June 2022, 7th

Phost'in Therapeutics (Montpellier, France), a biotech company focused on the discovery and development of N-glycosylation inhibitors for the treatment of cancer and other serious diseases, today announced the French National Agency for the Safety of Medicines and Health Products (ANSM) and the Italian Medicines Agency (AIFA) have accepted an adaptive Phase I/II in patients with advanced solid tumors for the First-In-Class selective n-glycosylation inhibitor, PhOx430 (the PhAST trial).

PhOx430 targets a key glycosylation mechanism responsible for supporting cancer proliferation and suppressing the immune response. The program has demonstrated a significant antitumoral efficacy in several animal models, associated with a promising safety profile in regulatory preclinical studies.

The PhAST trial will begin enrolling two dozen of patients with non-selected tumour types in a dose escalation phase, followed by three expansion cohorts gathering patients with selected tumour types, including Glioblastoma multiforme (GBM), Triple-negative breast cancers (TNBC) and a selection of other solid tumour types, for which few therapeutic options exist.

The primary objective will be to determine the safety and tolerability of PhOx430 in patients. The secondary objectives will include a preliminary evaluation of efficacy, in addition with the identification of biomarkers.

In France, the CTA was submitted and accepted as part of ANSM's Fast Track procedure designed to reduce processing times for clinical trial authorization requests for innovative medical products.

Karine Chorro, CEO of Phost'in Therapeutics, said: *"The approval of this CTA marks an important regulatory milestone for PhOx430. We are grateful to the French and Italian Competent Authorities for their positive feedback on what we believe is a disruptive clinical innovation, and a formidable hope for patients with limited therapeutic options. We will continue our efforts to advance PhOx430 clinical development, and to bring it to patients and their families."*

GBM, still a rare disease with a global incidence rate inferior to 10 per 100,000 in Europe and North America, remains one of the most aggressive malignant cancer types, difficult to treat and associated with high mortality. The life expectancy of GBM patients is typically less than 15 months after diagnosis. TNBCs represent 10-15% of all breast cancers, are typically associated with a high risk of early metastasis, including brain metastases, and bad 5-year prognostic. Therefore, there is a critical and unmet therapeutic need for both indications.

The clinical program received the scientific contribution of Gianni Bonadonna Foundation, which collaborated in the conception and design of the research protocol. *"The approval of this trial represents the actualization of one of the main goals of the Gianni Bonadonna Foundation: to endorse therapeutic innovation from the earliest phases of research, to achieve the best results in favor of cancer patients"* declared **Dr. Luca Gianni, President of Gianni Bonadonna Foundation.**

Dr. Diego Tosi, Gianni Bonadonna Foundation's scientific coordinator and head of the Early Clinical Trial Unit - Medical Oncology Department of the Cancer Institute of Montpellier in France, has been entrusted with the international direction of this first-in-human clinical trial, conducted in French and



Italian Oncological Centers. *"This is the first drug with this type of mechanism of action",* Diego Tosi explained. *"The antitumor action seems mainly due to the effect on the membrane receptors, and the drug is highly effective in the preclinical setting; there are less data on how the immune response is modified, but our research will try to find answers".*

Phost'in Therapeutics has also appointed contract research organization ("CRO") Michelangelo Tech Srl (Milan, Italy) to coordinate the PhAST trial. Owned by the Michelangelo Foundation with the aim of contributing to progress in cancer research and improving treatment options for tumors, Michelangelo Tech Srl provides extensive expertise in early phase clinical development, precisely to favor the rapid clinical application of new therapies.

About PhOx 430 treatment

The aberrant, complex and hypersialylated glycosylation of tumor cells is now recognized as a novel immune checkpoint, affecting key membrane receptors and masking tumor cells from the immune system, via the formation of complex abnormal glycan patterns operating as a shield. PhOx430 targets this aberrant glycosylation directly to the source through selective inhibition of a specific enzyme for a double antitumor effect, inducing simultaneously an anti-cancer immune response and the down regulation of the main receptors implicated in cancer. PhOx430 is the first program from the *Phost'Screen*TM platform that combines unique and patented chemical libraries with cutting-edge screening tools to produce selective n-glycosylation inhibitors.

About Phost'in Therapeutics

Phost'in Therapeutics is a biotechnology company specialized in the discovery and development of NCE's specifically targeting abnormal pathogenic glycosylation mechanisms. Its PhOx430 program has just been approved in Europe for authorization of a multicentric clinical trial for patients suffering of advanced solid cancers. The company also leads upstream research programs in several other diseases using its unique expertise and discovery platform *Phost'Screen*TM. Spin-off of the academic world, Phost'in disposes, in addition to its own patents, of an exclusive license for two families of academic patents owned by CNRS (Centre National de la Recherche Scientifique), ENSCM (Ecole Nationale Supérieure de Chimie de Montpellier), and the Universities of Montpellier, Sorbonne Paris Nord and Paris Saclay. Based in Montpellier, France, the company was awarded a national Special Prize in the 2014 ILab competition of the French Research Ministry at its creation and has since raised €12m in equity, mainly from international funds, including Remiges Ventures (US), Anri (Japan) and Irdi Capital Investissement (France) with the renewed support of bpifrance, LifeScience cluster Eurobiomed, Region Occitanie and Montpellier Med Vallée. www.phostin.com

About Gianni Bonadonna Foundation

Fondazione Gianni Bonadonna was launched to honor and pursue the legacy of Gianni Bonadonna, founding father of modern oncology who developed key new therapies for women with breast cancer and patients with lymphomas. Fondazione Gianni Bonadonna's mission is to promote therapeutic innovation from the earliest phases of research and support the education of new generations of physician-scientists in oncology. www.fondazionebonadonna.org

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