



## **PHOST'IN THERAPEUTICS AND THE GIANNI BONADONNA FOUNDATION ANNOUNCE OPENING OF 2 EXPANSION COHORTS IN THE PHAST TRIAL, AN ADAPTIVE FIRST-IN-HUMAN TRIAL IN PATIENTS WITH ADVANCED SOLID TUMORS.**

*Montpellier, France – January 2025, 13th*

**Phost'in Therapeutics (Montpellier, France), a clinical-stage biotechnology company focused on discovery and development of N-glycosylation inhibitors for the treatment of cancer and other serious diseases, today announced a significant achievement in the clinical evaluation of its first-in-class selective N-glycosylation inhibitor, PhOx430. This milestone marks the dosing of the first patients in the Cohort Expansion phase of the PhAST trial, an adaptive Phase I/II study designed to evaluate PhOx430 in patients with advanced solid tumors. The trial is being conducted with the scientific contribution of the Gianni Bonadonna Foundation which collaborated in the conception of the research protocol.**

The Protocol Steering Committee (PSC) of the PhAST clinical trial unanimously approved the launch of the Cohort Expansion phase on November 28th, 2024. This decision was based on favorable interim results from the Dose Escalation phase, which enrolled 21 patients with all types of solid tumors. The 2 expansion cohorts will further evaluate the recommended Phase 2 dose regimen of PhOx430 and provide a broader assessment of the treatment's safety and preliminary efficacy in a larger and more homogeneous patient population. The trial is expected to enroll respectively 23 patients with glioblastoma and 30 patients across a range of selected tumors, including serous ovarian carcinoma, gastric and esophageal cancers, hepatocellular carcinoma, head and neck cancers, non-small cell lung cancer (NSCLC), and pancreatic cancers.

The PhAST trial is designed to evaluate the safety and pharmacodynamic effects of PhOx430 in patients. Additional objectives include a preliminary assessment of efficacy and the identification of potential biomarkers. Beyond its scientific significance, this trial also marks the first time a selective N-glycosylation inhibitor has been administered to patients, representing a step forward in the fight to overcome cancer and immune resistance through groundbreaking therapeutic approaches.

*"The opening of the Cohort Expansion phase of our Phase I/II trial marks a key milestone in our clinical development" said **Karine Chorro, CEO of Phost'in Therapeutics**. "We are thrilled to broaden the evaluation of PhOx430 and continue our commitment to providing innovative therapeutic solutions targeting the aberrant glycosylation of tumors in patients facing limited treatment options."*

**Dr. Alain Herrera, MD, CMO of Phost'in Therapeutics**, added, *"We are encouraged by the favorable safety profile and the initial signs of activity observed with PhOx430 during the dose-escalation phase of the trial across a diverse patient population. We look forward to further evaluating the recommended Phase 2 dose regimen of PhOx430 in larger cohorts of patients with selected solid tumors."*

**Dr. Diego Tosi, MD, PhD, Scientific Coordinator of Gianni Bonadonna Foundation and Head of the Early Clinical Trial Unit at the Institut regional du Cancer de Montpellier (France)**, is the international chair of the PhAST study. He reckoned that *"PhOx430 is a promising drug, as it characterized by an innovative mechanism of action, a solid preclinical background data and a target potentially present in a wide number of solid cancers"*.



Symbolically, the first patients in these cohorts have been enrolled at the Institut regional du Cancer de Montpellier (Montpellier, France), the clinical site at which Dr Tosi is the Principal Investigator. Other clinical centers involved include the Ospedale San Raffaele (Milan, Italy), which also contributed to the Dose Escalation phase, as well as the Istituto Nazionale dei Tumori (Milan, Italy) and the Centro oncologico de ematologico di Reggio Emilia (Reggio Emilia, Italy), which are joining the study.

The contract research organization ("CRO") Michelangelo Tech Srl (Milan, Italy) has been retained 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. In parallel, Phost'in Therapeutics has selected Leads to Development (L2D, Paris, France), an agency with a strong reputation across Europe and the United States for regulatory and development expertise, to support product development strategy definition, operations and filings

### **About PhOx 430**

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 to the immune system, via the formation of complex abnormal glycan patterns operating as a shield. PhOx430 targets this aberrant glycosylation directly to its source through selective inhibition of the enzyme GnT-V, inducing simultaneously an anti-cancer immune response and the down regulation of the main receptors implicated in cancer progression. The program has demonstrated a significant antitumoral efficacy in several animal models, associated with a promising safety profile in regulatory preclinical studies. It is the first program from the *Phost'Screen*<sup>TM</sup> platform that combines unique and patented chemical libraries with cutting-edge screening tools to produce selective n-glycosylation inhibitors.

### **About the 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](http://www.fondazionebonadonna.org)

### **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. In addition to PhOx430 clinical development, the company leads upstream research programs in several other diseases using its unique expertise and discovery platform. A spin-off of the academic world, Phost'in possesses, in addition to its own patents, 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 received the renewed support of France 2030, bpifrance, LifeScience cluster Eurobiomed, Region Occitanie and Montpellier Med Vallée.

For more information about Phost'in Therapeutics, please visit [www.phostin.com](http://www.phostin.com) and/or contact:

**Karine Chorro, CEO & Richard Meadows, CBO**

**[contact@phostin.com](mailto:contact@phostin.com)**

**Phost'in Therapeutics SAS, 104 rue de la Galera, 34 090 Montpellier FRANCE**