PRESS RELEASE

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FUNCTIONAL PRECISION MEDICINE

SIRIUS NEOSIGHT AND CENTRE LÉON BÉRARD LAUNCH A CLINICAL STUDY TO PREDICT RESPONSE TO CANCER TREATMENTS BY GROWING TUMOR TWINS FROM A SIMPLE BLOOD DRAW

Sirius Neosight, a French start-up specializing in tumor analysis from a blood draw, and the **Centre Léon Bérard** announce the launch of the **E-FACToR** clinical study. This study aims to improve the personalization of cancer treatments.

Sirius Neosight, a pioneering French start-up in functional liquid biopsy capable of growing a patient's tumor cells directly from a blood draw to redevelop living replicas of their tumor, and the **Centre Léon Bérard**, a world-renowned oncology reference center based in Lyon, announce the official launch of the **E-FACToR** clinical study (*Enumeration and Functional Analysis of Circulating Tumor Cells for Homologous Recombination*). This prospective, single-center study, approved by the Sud-Est II Committee for the Protection of Persons in February 2026, marks a major step forward for functional personalized medicine applicable from a simple blood draw.

The E-FACToR study aims to better understand why some patients respond to treatments and others do not, in order to tailor therapies more precisely. Specifically, it seeks to establish whether a measurement taken on tumor cells collected from the blood — without a biopsy — can predict treatment efficacy. It will notably assess the correlation between the **functional status of homologous recombination (HR), a key DNA repair mechanism on which sensitivity to PARP inhibitors depends,** measured in circulating tumor cells (CTCs) and progression-free survival (PFS) in patients treated with PARP inhibitors and/or platinum-based chemotherapy. It will involve 300 patients with advanced or metastatic breast, prostate, ovarian, and pancreatic cancers, followed at the Centre Léon Bérard.

Today, predicting response to treatment remains difficult despite existing biomarkers. Some chemotherapies and targeted therapies — such as PARP inhibitors — are highly effective in some patients with breast, ovarian, prostate, or pancreatic cancer, but not in all. Current genetic analyses (BRCA mutation, HRD score) are not sufficient to explain these differences: some patients without a known mutation respond, while others with a mutation do not benefit. What is missing is a test capable of directly measuring the living behavior of each patient's tumor cells — rather than simply reading their DNA.

This is precisely where Sirius Neosight's technology platform comes in. From a simple blood tube (10 mL) collected during a routine consultation, CTCs — those rare tumor cells that circulate in the blood and reflect the tumor's current state — are isolated with unmatched sensitivity (fewer than 5 cells per 10 mL), then amplified ex vivo to form 3D tumor twins in under three weeks — true living miniatures of the patient's tumor, reflecting its state at the time of treatment. These 3D tumor twins then make it possible to directly test how tumor cells repair their DNA: a key functional indicator that cannot be obtained by reading the genome alone. This is a first in this clinical context.

A DIFFERENTIATING POSITION IN THE PRECISION MEDICINE LANDSCAPE

Precision medicine today relies mainly on reading the tumor's genetic code: a useful but static snapshot that does not reveal how the tumor actually behaves in response to treatment. Sirius Neosight goes further: from a simple blood draw, it isolates the living tumor cells circulating in the blood — true mirrors of the tumor at its current stage of development — and cultures them to form **3D tumor twins**: living micro-replicas of the patient's tumor, grown *ex vivo*. These 3D tumor twins make it possible to directly test the response to treatments on the patient's own cells — and to repeat this test with each blood draw, to track the tumor's evolution throughout treatment. It is this unique combination — ultra-sensitive liquid biopsy **and** 3D tumor twins from CTCs — that Sirius Neosight achieves from a single blood sample:

1. **Ultra-sensitive liquid biopsy**: capable of detecting and capturing CTCs even when present at fewer than 5 cells per 10 mL of blood, achievable at every consultation without any invasive procedure.
2. **Production of 3D tumor twins from CTCs**: living mini-replicas of the patient's tumor, grown from circulating cells in under three weeks. These 3D tumor twins reflect the tumor's real, current state — far beyond what a tissue biopsy performed months earlier can reveal — and make it possible to reproduce *ex vivo* each patient's individual tumor biology in order to directly test treatments.
3. **Functional testing on 3D tumor twins from CTCs**: a test performed directly on the patient's living cells, measuring their ability to repair their DNA — the key mechanism on which their sensitivity to targeted treatments depends. A real-time functional indicator, where genetics alone falls short.

This combination is unique: Sirius Neosight is a **unique player** able to **combine, from a single blood sample, ultra-sensitive liquid biopsy AND 3D tumor twins from circulating tumor cells**. Where genomic analyses read the tumor's DNA, Sirius Neosight brings its cells to life and observes how they react — offering a dynamic, repeatable, and functional window into each patient's tumor biology, in real time throughout their treatment.

E-FACTOR : A FOUNDATIONAL CLINICAL STUDY

Designed as a translational proof-of-concept study, E-FACToR represents the first milestone in a two-pronged clinical strategy:

1. **Longitudinal monitoring of CTC enumeration** as a reflection of tumor burden evolution;
2. **Functional assessment of HR status** in amplified CTCs, to anticipate response to PARP inhibitors and genotoxic chemotherapies.

The study, led by Dr. Hélène Vanacker and Dr. Marie Laurent, medical oncologists at the Centre Léon Bérard (coordinating investigators), and Dr. David Pérol, biostatistician and Director of Clinical Research at the Centre Léon Bérard (sponsor's representative), will enroll 300 patients over 24 months, with a minimum follow-up of 18 months. The Centre Léon Bérard, sponsor of the study, will rely on Sirius Neosight's analytical expertise for all biological analyses of CTCs.

ABOUT THE SIRIUS NEOSIGHT PLATFORM

Sirius Neosight is a French biotechnology start-up, hosted at the Centre Léon Bérard, which has developed a unique technology: capturing circulating tumor cells (CTCs) — rare cells that the tumor releases into the blood — and growing them to create functionnal 3D tumor twins, tiny living replicas of the patient's tumor. This approach makes it possible to observe and test, directly on the patient's living cells, how their tumor responds to treatments — without surgery or invasive biopsy. Sirius Neosight is the only French start-up combining, from a simple blood draw, the capture and culture of living circulating tumor cells (fewer than 5 CTCs per 10 mL) into 3D tumor twins in under three weeks. These 3D tumor twins — grown from the patient's own living circulating tumor cells — reflect the tumor's real, current state, far beyond what a tissue biopsy performed months earlier can reveal. Unlike genomic analyses (which read DNA without observing cellular behavior) or 3D tumor twins grown from biopsied tissue (invasive, one-off, and difficult to repeat), the Sirius Neosight platform offers a living, dynamic, and personalized reading of tumor biology — repeatable with every blood draw to track the patient's progress throughout their treatment.

ABOUT CENTRE LÉON BÉRARD

A world-renowned cancer center, the Centre Léon Bérard is dedicated to the care of cancer patients and to fundamental, clinical, and translational oncology research. With more than 2,500 healthcare professionals, it welcomes over 40,000 patients each year and conducts numerous innovative clinical trials. The Centre Léon Bérard is affiliated with the Unicancer network, the French federation of cancer centers.

PRESS CONTACTS :

SIRIUS NEOSIGHT : CEO — a.bastid@sirius-ns.com

CENTRE LÉON BÉRARD : Communication department — presse@lyon.unicancer.fr