CALYM

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INSTITUT CARNOT CALYM

Advancing innovation in lymphoma

CALYM is a nonprofit research institute that offers a unique R&D approach in lymphoma treatments and diagnostics, spanning from new target identification to large international phase 3 clinical trials.

Lymphoma is the sixth most common cancer and the most common form of hematologic malignancy in the developed world. Researchers have identified more than 60 distinct entities of this cancer, each with specific diagnostic, evolutionary and therapeutic features. Lymphoma can be cured in around 50% of patients; however, success rates for therapy vary considerably, and some types of this oncologic disease remain incurable.

Significant medical and R&D challenges must be overcome for the development of better-tolerated and more effective lymphoma drugs, as well as relevant biomarkers, and for the goal of personalized medicine to be achieved. The Consortium for the Acceleration of Innovation and its Transfer in the Lymphoma Field (CALYM) is a nonprofit research institute that brings together 15 organizations with complementary expertise in preclinical, translational and clinical lymphoma research. The institute focuses on addressing unmet medical needs in this field through research partnerships with industry and other R&D organizations.

Global leader in lymphoma

Headquartered in Lyon, France, CALYM received accreditation as a 'Carnot institute' from the French Ministry for Higher Education and Research in 2011. The prestigious Carnot label is awarded to public/parapublic research institutes that combine scientific excellence with professionalism and are committed to fostering innovation with industry partners.

CALYM includes a network of over 130 clinical investigation centers linked to the Lymphoma Study Association (LYSA), an international leader of lymphoma research with 750 member physicians and over 30 years of experience in the clinical and translational fields. Each year, around 1,000 patients participate in LYSA clinical trials across its centers in France, Belgium and Portugal, as well as those of its academic partners across four continents. Trials are designed to assess the efficacy and safety of new agents and drug combinations for specific subtypes of lymphoma and different stages of the disease.

LYSA has treated almost 30,000 patients through many clinical programs. Among these programs, LYSA performed the pivotal phase 3 study that led to registration of rituximab as a lymphoma treatment. The group has also been instrumental in the development of the widely used International Prognostic Index and Follicular Lymphoma International Prognostic Index; the identification and validation of numerous genetic, molecular and imaging lymphoma biomarkers; the definition of response criteria; and the identification of surrogate endpoints. LYSA also had a key role in the development and standardization of positron-emission tomography–computed tomography use in lymphoma staging and response assessment.

The Lymphoma Academic Research Organisation (LYSARC) is a fully integrated academic clinical research organization—the largest in Europe in this field—and is the operational and contract body for CALYM's clinical programs. It is accredited as a 'Data Management Center' by the French National Cancer Institute and has the capacity and skills to run clinical trials from phase 1 (including first in human) to phase 3 (including international registration trials) in France and internationally. The capabilities of LYSARC include project management, regulatory affairs, monitoring, data management, biostatistics, pharmacovigilance, quality control, central pathology and imaging reviews, and biology sampling logistics. LYSARC also conducts long-term follow-up studies of clinical trials, cohort studies and post-authorization safety studies.

There are also 13 CALYM research teams based at universities and hospitals across France working on the pathophysiology of normal and neoplastic lymphoid tissue and the discovery of new therapeutic targets and agents (see CALYM's website for more details). CALYM researchers study signaling pathways, such as those involving protein kinases, apoptosis and oncogenetic factors (transcription, epigenetics and noncoding RNAs), and search for the genetic alterations associated with lymphomas specific subtypes. They also investigate host and tumor cross-talk within the tumor niche through molecular and functional approaches and study the alterations of innate immunity associated with cancer, along with ways to circumvent them using biotherapies.

Four R&D pillars

CALYM has structured its R&D activities around four pillars: the identification and validation of new biological targets and *in vitro*/*in vivo* models for preclinical development of drug candidates; the identification, validation, patenting and licensing of blood and tissue biomarkers for different types of lymphoma to improve diagnostics, guide therapy decisions and predict tumor responses; the identification of early signals of pharmacologic activity during phase 1/2 clinical trials to accelerate translational research; and the optimization of clinical-research-related tools, processes and platforms to accelerate development, registration and market access of drug candidates.

The integrated expertise and competencies found within CALYM enable it to cover all stages of lymphoma R&D for therapeutics and biomarkers, from the identification of new biological targets through to phase 3 clinical trials and beyond.

Partnering opportunities

CALYM offers a broad range of opportunities for partnering in the lymphoma field. One option is access to CALYM's scientific expertise and platforms on a contract basis. CALYM also collaborates with partners on a wide range of preclinical and clinical projects (**Box 1**). The institute has successful international partnering experience across the industry, from pharmaceutical leaders to emerging biotechnology or *in vitro* diagnostic companies, and is International Organization for Standardization 9001:2008 certified for the management and monitoring of partnering research activities.

Box 1: CALYM's partnering examples

- CALYM is conducting, in partnership with a global biopharmaceutical company, the clinical program for an anticancer agent in combination with CHOP therapy for patients with peripheral T cell lymphoma, from phase 1 through to pivotal phase 3 international studies.
- CALYM recently developed and patented a reverse transcriptase–multiplex ligation–dependent probe amplification assay for differentiating diffuse large B cell lymphoma subtypes, which is open for licensing.
- CALYM assets include the unique CeVi lymphoma viable cell collection, which contains cryopreserved cell suspensions from more than 600 malignant and nonmalignant lymphoid samples that can be used for screening assays.
- Another option is to access CALYM's databases (including a proprietary database of over 20,000 patients with lymphoma) and biological collections on a research collaboration basis, for studies such as data mining, meta-analyses, surrogate endpoints, translational research and bioinformatics.
- Partners may also access CALYM's technology platforms on a research collaboration basis. These assets include a histopathology laboratory dedicated to lymphoma, imaging platforms, flow cytometry platforms and 'omics' platforms, such as large-scale sequencing and transcriptomics.

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