BGDO
Belgian Group
of Digestive Oncology

Press release

Launch of the international SAFIR ABC10 program for patients with biliary tract cancer

Unicancer, University College of London (UCL) and the Belgian Group of Digestive Oncology (BGDO) announce the launch of the flagship SAFIR ABC10 study, an international precision medicine project for patients with advanced biliary tract cancer, which opens access to targeted therapies in the maintenance setting to meet a strong medical need.

Patients with biliary tract cancers: a priority for academic research

Biliary tract cancer, and in particular cholangiocarcinoma, has increased in frequency over the last 30 years, placing it 6th among the most common cancers in the world (together with liver). Treatment for advanced biliary tract cancer is based on chemotherapy, recently supplemented by immunotherapy. Despite this progress, overall survival stagnates dramatically around one year, highlighting an urgent need to identifying innovative and effective alternatives to improve the model of care.

For Unicancer, and the academic digestive oncology groups PRODIGE (France), NCRI UGI CSG (UK) and BGDO (Belgium), tackling this issue and responding to the medical need constitutes a research priority. This shared vision led to the development of the **SAFIR ABC10 program**, a project as ambitious as it is promising.

In this context, the Unicancer/UCL/BGDO alliance is pleased to have opened to recruitment (in UK and France) the SAFIR ABC10 study, the first precision medicine study in advanced biliary tract cancers, constructed to offer a panel of **7 targeted therapies** according to the specific abnormalities identified in the tumour.

The project was made possible in Belgium thanks to funding from the Foundation Against CancerFondation contre le Cancer and support from the various pharmaceutical, laboratories and biotechnology companies involved in the study. Belgium plans to open the study for recruitment by the end of 2024 in University Hospital Antwerp (UZA), Clinique Universitaires Saint-Luc, Hôpital Universitaire de Bruxelles (HUB) and UZ Leuven.

SAFIR ABC 10: bringing precision medicine to patients with biliary tract cancer

“The objective of this study is to demonstrate that the precision medicine approach, introduced as maintenance after standard chemotherapy and immunotherapy, can prolong the progression-free survival of patients. Given the poor prognosis at relapse, improving on the effectiveness of the first line treatment by integrating **matched targeted therapies** could constitute a breakthrough innovation in the current model of care at diagnosis. Especially since biliary tract cancers lend themselves particularly well to this due to their high number of actionable genomic alterations” reports Dr David Malka, Medical Oncologist at the Institut Mutualiste Montsouris in Paris, and Chief Investigator of the study.

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The SAFIR-ABC10 study entitled “Molecular targeted maintenance therapy versus standard of care in advanced biliary cancer: an international, randomised, controlled, open-label, platform phase 3 trial” (NCT05615818) is currently anticipated to recruit participants across 48 hospitals within the PRODIGE network in France, 15 NHS Trusts in the United Kingdom and 4 hospitals in Belgium.

Access to genomic profiling

The SAFIR-ABC10 study aims to recruit 800 participants in total, all of whom will benefit from genetic profiling of their tumour.

Both France and the United Kingdom have integrated access to genomic profiling on tumour tissue into the care pathway for advanced cancers. A characterisation of circulating tumour DNA **(liquid biopsy** on Guardant360®CDx) will complement the tissue profiling for all patients.

“In Belgium, the use of genomic profiling is not yet established in standard practice for our patients. The deployment of SAFIR ABC10 constitutes **a unique opportunity** for our patients to benefit from **tumour molecular characterization and innovative treatments** which they would not normally have been able to access in Belgium” underlines Professor Ivan Borbath, Gastrointestinal Oncologist at the Cliniques universitaires Saint-Luc in Brussels and Belgium Lead Investigator.

“The common pitfall for doctors when faced with profiling their patients is the absence of an accessible therapeutic option. The SAFIR-ABC10 study resolves this problem by providing a portfolio of molecules covering the majority of actionable targets recognized as being of clinical interest by ESCAT. A way to meet patient expectations, and to demonstrate that precision medicine is truly beneficial in this indication,” comments Professor John Bridgewater, Medical Oncologist at University College London Hospitals NHS Foundation Trust and UK Lead Investigator.

Patients with tumours carrying actionable alterations – FGFR2 (fusions/rearrangements, mutations), IDH1 (mutations) HER2 (amplifications, mutations), BRAF (V600E mutation) – may be treated with targeted therapies (futibatinib, ivosidenib, zanidatamab, trastuzumab & neratinib, encorafenib & binimetinib), alone or in combination after randomisation. In total 159 patients are expected to be randomised (2:1) between targeted therapy and continuation of standard chemotherapy with Cisplatin & Gemcitabine (CISGEM) +/- durvalumab (immunotherapy).

SAFIR-ABC10: a platform study

Following the launch of the SAFIR-ABC10 study, other ancillary clinical studies are in preparation to form a **unique research program**. “We note that the launch of SAFIR ABC10 acts as a catalyst for initiatives in this indication, which has been neglected by manufacturers for a very long time. The prospect of having a large, well-characterized population channelled into such a project has aroused a lot of interest,” rejoices Julien Edeline, Medical Oncologist at the Centre Eugène Marquis in Rennes.

Other first-line and second-line studies in populations without an actionable target are under development and should be added to the central SAFIR-ABC10 project in the next 12 months.

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