PRESS RELEASE

ASCO 2025 – Oral abstract session

Villejuif, 31 May 2025

A NEW DRUG TESTED AS A FIRST-LINE TREATMENT FOR POOR-PROGNOSIS EWING SARCOMAS

Regorafenib is a new drug that helps slow the progression of certain cancers by blocking the signals tumour cells need to grow and form new blood vessels. As part of the Rego-Inter-Ewing-1 study, sponsored by Gustave Roussy, this molecule was tested from the outset of treatment, in combination with standard chemotherapy, in patients with multi-metastatic Ewing sarcoma – a condition with a grim prognosis and few therapeutic options. ***The results, presented at the ASCO congress by Dr Pablo Berlanga, offer new hope in the treatment of this bone cancer, which mainly affects children, adolescents, and young adults.***

Abstract No. 10008 presented orally by Dr Pablo Berlanga on Saturday, 31 May at 17:24 UTC -5.

This oral presentation is one of the 109 presentations featured in the 2025 ASCO programme with contributions from Gustave Roussy's physician-scientists. Gustave Roussy is active across numerous areas of expertise, reflecting both the high quality of the research carried out at the Institute and its international standing.

Ewing sarcoma is the second most common malignant bone tumour in France. It mainly affects children, adolescents, and young adults, with two-thirds of patients aged between 5 and 25. The most important prognostic factor at diagnosis is the presence of metastases. Patients with extrapulmonary metastases face a particularly poor outlook, with a three-year progression-free survival rate of just 20%.

To improve outcomes for these high-risk patients, the EURO EWING consortium is committed to developing and evaluating new therapeutic approaches from the very first line of treatment. The goal is to ensure that young patients benefit from therapeutic innovations at the outset of their care. This approach stands in contrast to traditional early-phase clinical trial protocols, which typically reserve access to innovative treatments for relapse situations.

It is in this context that the Rego-Inter-Ewing-1 study was launched, sponsored by Gustave Roussy, with results presented in an oral session at the ASCO 2025 Congress by Dr Pablo Berlanga, paediatric oncologist at the Institute. It is an international, multicentre phase Ib trial, designed to assess the combination of standard chemotherapy and a new therapy, regorafenib, as a first-line treatment for patients diagnosed with multi-metastatic Ewing sarcoma.

A Feasible Combination

Regorafenib is a tyrosine kinase inhibitor that has shown some efficacy as a monotherapy, albeit limited, in relapsed Ewing sarcoma. The aim of the Rego-Inter-Ewing-1 trial is to combine it with chemotherapy from the outset, as part of first-line treatment. To this end, the study assessed the feasibility of combining regorafenib with standard VDC/IE chemotherapy in Ewing sarcoma.

A total of 13 patients aged between 8 and 23 years were recruited across seven centres in France, Australia, and the Netherlands. Early results show that the combination is well tolerated, with only one dose-limiting toxicity observed and no unexpected adverse events reported.

The Rego-Inter-Ewing-1 study has made it possible to determine the maximum tolerable dose of regorafenib for young patients.

This research was made possible with support from the 2021 Fight Kids Cancer call for projects. Regorafenib was provided by Bayer.

"These results support the upcoming launch of a European phase III trial, which will compare the regorafenib/chemotherapy combination to chemotherapy alone in all newly diagnosed multi-metastatic Ewing sarcomas," concludes Dr Berlanga. This new trial is expected to open in France by the end of 2025.

Abstract no. 3507

Phase Ib study of the combination of regorafenib with conventional chemotherapy in patients with newly diagnosed multi-metastatic Ewing sarcoma: The Rego-Inter-Ewing-1 study.
Oral abstract session presented by Dr Pablo Berlanga.
Saturday, 31 May 2025 | 16:57 UTC-5.

About Gustave Roussy

Ranked first in France, first in Europe and fourth in the world, Gustave Roussy is a centre of global expertise entirely dedicated to patients living with cancer. The Institute is a founding pillar of the Paris Saclay Cancer Cluster. Source of therapeutic innovations and diagnostic breakthroughs, the Institute welcomes nearly 50,000 patients each year, including 3,500 children and adolescents, and develops an integrated approach combining research, care and teaching. An expert in rare cancers and complex tumours, Gustave Roussy treats all cancers at all stages of life. It offers its patients personalised care that combines innovation and humanity, taking into account both care and the physical, psychological and social quality of life. With 4,100 employees at two sites, Villejuif and Chevilly-Larue, Gustave Roussy brings together the expertise essential for high-level cancer research; 40% of treated patients are

included in clinical studies. To find out more about Gustave Roussy and follow the Institute's news: www.gustaveroussy.en, X, Facebook, LinkedIn, Instagram and Bluesky.

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