**PRESS RELEASE**

**EMBARGOED UNTIL 30/09 - 14h45**

# REGOBONE: median PFS of 19.4 weeks with Regorafenib for metastatic chondrosarcoma patients after failure of prior chemotherapy

**[ESMO 2019 – 30 September] – Unicancer and the French Sarcoma Group are delighted to reveal the REGOBONE study results presented at the ESMO conference in Barcelona.**

## Chondrosarcoma (CS): the most common bone sarcoma in adults

This disease has an overall bad prognosis once metastatic and/or recurrent, with an expected median Progression Free Survival (PFS) of 4.7 months *(Italiano A, 2013).* There is an unmet medical need in this population of patients for who no standard systemic therapy exists. Validating new therapeutic options is therefore highly expected.
A strong biologic rationale exists for angiogenesis inhibition in chondrosarcoma, based on preclinical and clinical data in CS.

## REGOBONE: a randomized, double blinded non-comparative phase II trial

The academic REGOBONE study, coordinated by Pr. Florence Duffaud, oncologist at Hôpital La Timone, Marseille, and sponsored by Unicancer, has been designed to investigate the antitumor activity of regorafenib (STIVARGA®) - a potent inhibitory action against VEGF, PDGF and KIT receptors - in terms of centrally confirmed PFS according to RECIST 1.1, in locally advanced or metastatic relapsed adult bone sarcoma.
REGOBONE evaluates the activity in bone sarcoma histologies in 4 independent cohorts: osteosarcoma (n=43 patients), chondrosarcoma (n=40), Ewing sarcoma (n=36) and chordoma (n=24).
*"REGOBONE has already brought demonstration of regorafenib interest in the treatment of refractory osteosarcoma patients (Duffaud F, 2018)", reminds Pr. Duffaud. "The results presented today in Barcelona for the chondrosarcoma cohort show a promising activity as well".*

## A promising signal of activity with regorafenib for metastatic chondrosarcoma patients after failure of prior chemotherapy

The primary endpoint was the non-progression rate at 12 weeks. At this time, 54% (13/24) [35.8; +∞[ of the patients were non progressive on regorafenib, and 31% (5/16) [13.2; +∞[ on placebo. The median PFS was 19 weeks with regorafenib and 8 weeks with placebo, and the difference in non-progression rate was maintained at 24 weeks (47% versus 25%, respectively).

Considering the aggressiveness of this disease, these results indicate interesting activity of regorafenib for metastatic CS patients after failure to prior conventional chemotherapy, with positive impact on delaying disease progression, and an acceptable tolerance profile.

## About Unicancer

Unicancer is the only French hospital network 100% dedicated to the fight against cancer and the only national hospital federation dedicated to oncology.

Unicancer is also the leading national academic sponsor of clinical trials in oncology in Europe. Its Research and Development Department is responsible for implementing its overall research strategy. She is ISO 9001 certified for her clinical research.

**Key figures 2018:** 18 French Cancer Comprehensive Centers (FCCC), private non-profit health establishments, spread over 20 hospital sites in France, also certified for their clinical research; 540,000 patients per year (short-stay, HAH and external procedures); 1/3 of French international publications in the field of oncology (source: bibliometric study/ Thomson Reuters); 90 active clinical trials promoted by Unicancer's R&D, 54 of which are in recruitment, involving more than 6,300 patients included in 200 research centres, 40 of which are abroad; more than 40,000 patients registered in the ESME real life data programme.

>> Follow us: www.unicancer.fr