

## 2SPD-006 ASSESSMENT OF REGORAFENIB, RAMUCIRUMAB AND CABOZANTINIB AS SECONDLINER THERAPY IN HEPATOCARCINOMA AND ALFA-FETOPROTEIN VALUE $\geq 400$ NG/ML

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**Background and importance** Regorafenib, ramucirumab and cabozantinib are used as secondline therapy in patients with hepatocarcinoma and alfa-fetoprotein value  $\geq 400$  ng/mL (HCC-AP  $\geq 400$ ). There are no direct comparisons among them.

**Aim and objectives** To establish whether regorafenib, ramucirumab and cabozantinib are equivalent therapeutic alternatives (ATE) in the secondline treatment of HCC-AP  $\geq 400$  through an indirect treatment comparison (ITC) using a common comparator.

**Material and methods** A search was conducted to identify phase III clinical trials with similar populations (secondline treatment of HCC-AP  $\geq 400$ ), duration and endpoints. If more than one study of the same drug was found, the results were combined in a meta-analysis (Joaquim Primo calculator). ITC was made according to Bucher's method. The variable selected to determine clinical equivalence was overall survival (OS). Delta value ( $\Delta$ ), maximum acceptable difference as a clinical criterion of non-inferiority, was set at 0.750 (and its inverse, 1.33), the value used in trials to calculate sample size. To establish positioning, the criteria of the ATE guide were applied. If 95% CI deviated from the delta margin, this probability was calculated using the Shakespare method.

**Results** Four clinical trials were found, ramucirumab (n=2), regorafenib (n=1) and cabozantinib (n=1). Limitations found: included population (only patients with alpha-fetoprotein  $\geq 400$  ng/mL versus all patients, then subgroup data were used for ITC) and previous therapy as firstline (only sorafenib vs other treatments allowed, in small percentages). Ramucirumab trials were pooled, resulting in HR 0.71 (95% CI 0.58 to 0.86). The results of the ITC are shown in table 1.

Abstract 2SPD-006 Table 1

Reference	OS (HR (95% CI))
Cabozantinib-regorafenib	1.044 (0.692 to 1.576)
Ramucirumab-regorafenib	1.044 (0.726 to 1.501)
Ramucirumab-cabozantinib	1 (0.712 to 1.405)

According to the ATE guide, there was a likely clinical equivalence. The probability that the result exceeded the delta margin above and below was, respectively, 12.45% and 5.76% for cabozantinib-regorafenib, 9.57% and 3.71% for ramucirumab-regorafenib, and 5% and 4.86% for ramucirumab-cabozantinib.

**Conclusion and relevance** The ITC showed no statistically significant differences in OS among the drugs. The 95% CI showed a certain grade of uncertainty, exceeding the equivalence margin. According to the ATE guide, there was clinical equivalence among the drugs due to the small percentage of 95% CI outside the equivalence margin.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

## 2SPD-007 OUT OF SUPPLY OF CHEMOTHERAPY INJECTABLE MEDICINES OVER 9 MONTHS: PATIENT IMPACT

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**Background and importance** For several years, healthcare facilities have noted an increase in out of supply medicines, including those in the oncology field.

**Aim and objectives** The aim of this study was to establish which chemotherapy injectable medicines were out of supply and determine the impact on patients.

**Material and methods** We took a census of chemotherapy injectable medicines out of supply between January and September 2019 from an Excel database indexing out of supply medicines, updated with information from laboratories or the national agency for medicines and healthcare product safety. Then, using patient files from Chimio and Easily software, we determined the patients affected by these out of supply medicines.

**Results** Three chemotherapeutic pharmaceutical specialities were identified as being out of supply in 2019: bleomycin, mitomycin (Ametycine) and docetaxel (Taxotere). Of the 285 patients treated by injectable chemotherapy in our healthcare facility, 7 were affected by these out of supply medicines and 1 patient was affected by 2 out of supply medicines.

For bleomycin, two patients with ovarian cancer did not have an alternative. For mitomycin, the treatment of two patients with bladder cancer had been delayed for 7 days and one patient with anorectal squamous cell carcinoma (SCC) had to change his protocol. For docetaxel, two patients (one with prostate cancer and one with anorectal SCC) did not have an alternative and one patient with prostate cancer had to change his protocol.

**Conclusion and relevance** The out of supply of chemotherapy injectable medicines requires patients to adapt to the treatment when the treatment should adapt to the patient. The out of supply medicines lead to loss of hope for patients, even if it is hard to quantify. One of the consequences is that we have to explain to patients why the treatment is different from the one initially planned and sometimes it can be difficult to reassure them. We can ask the question if there will be a decline in the quality of care of certain cancers in the coming years facing more and more regular out of supply medicines, sometimes with no alternative for the patient.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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## 2SPD-008 IMPACT OF FRENCH EXPERIMENT FOR INCENTIVISING ETANERCEPT BIOSIMILAR USE AFTER 10 MONTHS

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**Background and importance** In order to ensure the sustainability of the French healthcare system, the government launched