Randomized phase III study comparing FOLFOX + bevacizumab versus folfoxirI + bevacizumab (BEV) as 1st line treatment in patients with metastatic colorectal cancer (mCRC) with ≥3 baseline circulating tumor cells (bCTCs).

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Abstract Disclosures

Background:
FOLFOXIRI+BEV has demonstrated a survival benefit compared with FOLFIRI plus BEV (TRIBE Lancet Oncol 2015) in first-line mCRC. Nevertheless, due to its safety profile, this schedule is not recommended for all pts. In addition, we have showed that the detection of ≥3 bCTCs is a poor prognostic factor for survival (MACRO The Oncologist 2012). The VISNU-1 trial compares FOLFOX + BEV vs FOLFOXIRI + BEV in pts with mCRC and ≥3 bCTCs. Progression-free survival (PFS) is the primary endpoint. Secondary endpoints included overall response rate (ORR) and overall survival (OS).

Methods:
This is an open, multicentric, randomized phase III trial. Patients with mCRC younger than 70 years, ECOG 0-1 were randomized to FOLFOX+BEV (arm A) or FOLFOXIRI+BEV (arm B), stratified perKRAS mutation (mutated vs WT) and number of involved organs (1 vs >1).
Results:
349 pts were included in the ITT population; 177 in group A and 172 in group B. Characteristics of the pts, molecular profiling and safety analysis have been previously presented at ASCO 2018 and showed that this schedule had an acceptable toxicity profile. Efficacy analysis in the ITT population is shown in the table.

Conclusions:
In this population with very bad prognosis, our study met its primary endpoint. Pts who received FOLFOXIRI + Bev benefit for a statistically significative PFS and ORR. OS showed a trend of benefit in the experimental arm. According to these results, FOLFOXIRI-Bev could be considered an adequate treatment option for pts with mCRC and ≥3 bCTCs. Clinical trial information: 2012-000846-37.

<table>
<thead>
<tr>
<th>Variable</th>
<th>FOLFOX + Bev n=177</th>
<th>FOLFOXIRI + Bev n=172</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS (median in m)</td>
<td>9.3</td>
<td>12.4</td>
<td>0.0004</td>
</tr>
<tr>
<td>ORR (%)</td>
<td>52.0</td>
<td>59.0</td>
<td>0.1685</td>
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<tr>
<td>OS (median in m)</td>
<td>17.6</td>
<td>21.7</td>
<td>0.862</td>
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</tbody>
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Meeting:
2019 ASCO Annual Meeting

Session Type:
Oral Abstract Session

Session Title:
Gastrointestinal (Colorectal) Cancer

Track:
Gastrointestinal (Colorectal) Cancer

Subtrack:
Advanced Disease