ECOG E3201: Intergroup Randomized Phase III Study of Postoperative Irinotecan, 5-Fluorouracil (FU), Leucovorin (LV) vs Oxaliplatin, FU/LV vs FU/LV for Patients (pts) With Stage II/III Rectal Cancer Receiving Either Pre or Postoperative Radiation (RT)/FU

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ABSTRACT

Background: In the US patients with stage II/III rectal cancer routinely receive pre or postoperative RT/FU. To date, in addition to chemoradiation, standard (most frequently reported) Arm A: Arm S:
Arm A: 8 cycles FOLFIRI (180mg/m2) vs oxaliplatin 5FULV (n=28) FOLFOX (n=32)

Arm B: Chemo + RT

Grade Grade Grade Grade Grade Grade

I 3 4 3 4 3 4 3 4 3

Arm C: 5-FU/LV 4 cycles 8 cycles Oxaliplatin/5 -FU/LV 8 cycles

Arm D: Irinotecan/5 -FU/LV 4 cycles 4 cycles

Arm E: Oxaliplatin/5-FU/LV 4 cycles

Arm F: 5-FU/LV 1 cycle

Results: Information is reported for 95% of patients (170/179).

There was a trend towards more diarrhea and overall toxicity. There have been limited toxicity data reported thus far, FOLFOX as rectal adjuvant therapy is a common platform for new clinical trials, including the recently activated GI Intergroup adjuvant rectal cancer trial E5204. E3201 provides important comparative toxicity information demonstrating that FOLFOX can be safely administered to rectal cancer patients following chemoradiotherapy.

CONCLUSION

Although there have been limited toxicity data reported thus far, FOLFOX as rectal adjuvant therapy is a common platform for new clinical trials, including the recently activated GI Intergroup adjuvant rectal cancer trial E5204. E3201 provides important comparative toxicity information demonstrating that FOLFOX can be safely administered to rectal cancer patients following chemoradiotherapy.

Step 2 Post - Baseline Toxocities (most frequently reported)

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Arm A</th>
<th>Arm B</th>
<th>Arm C</th>
<th>Arm D</th>
<th>Arm E</th>
<th>Arm F</th>
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<tbody>
<tr>
<td>Nausea</td>
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<td>21</td>
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<tr>
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