**Session G. Head and neck cancer**

**G01** The phase III study INTERCEPTOR in locally advanced head and neck cancer (LA-HNC). Preliminary safety report


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**Background:** INTERCEPTOR is a randomized multicentre phase III study comparing CRT (Aldestein 2003) vs induction (Vermorken 2007) followed by RT and Cetuximab (bioRT)(Bonner 2006). The study started in October 2009. The maine objective is overal survival, secondary end-points are response rate, progression free survival, toxicities and role of biomolecular prognostic factors. Hereby we present the preliminary safety report of the study.

**Methods:** Naïve patients with LA-HNC histological proven, adequate bone marrow, renal and hepatic function and age > 18 yr old are eligible. Treatment consisted of:

- Arm A: docetaxel = 75 mg/mq, cisplatin (C) = 75 mg/mq day 1, FU c.i. = 750mg/mq 96h, every 3 weeks for 3 times then cetuximab loading dose 400 mg/mq followed by weekly 250mg/mq with a standard Radiotherapy (RT) program equivalent daily dose 2Gy up to 70 Gy. Arm B: C = 100 mg/mq day 1,22,43 concurrent with standard RT as in arm A. Statistic: We hypothesized to treat 278 pts to have a statistical power of 0.80 with a two tail design, α error < 0.05. The study will close on March 2016 and the final analyses will be provided by 2017. Hereby we report the safety analysis of the first 170 pts.

**Results:** INTERCEPTOR accrued 228 pts at March 31, 2015. The first 170 are considered in the present analysis (85 and 85 on Arm A and B). M/F were 70/15 and 66/19 in Arm A and B respectively. Toxicities are reported as the worst grade observed during the treatment. Haematological toxicities G1 + G2, G3 + G4 in Arm A and B were: leukopenia 23/8 and 33/6 (N.S.); neutropenia: 15/18 and 23/7 (p = 0.017); anemia: 61/2 and 54/3 (N.S.); thrombocytopenia were 20/0 and 12/1 respectively in arm A and arm B (N.S.). Stomatitis G1/2/3/4 were 9/32/28/4 and 14/26/23/1 (N.S.). Weight loss was classified using CTCAE 3.0. G1/2/3 weight loss was 25/10/2 and 25/12/2 in arm A and in Arm B respectively (N.S.). Radio-dermatitis G1/2/3/4 was 11/34/14/1 and 17/30/3/0 in Arm A and B (N.S.). Dysphagia G1/2/3 was reported in 9/16/11 and 10/10/15 patients at first post treatment clinical evaluation (N.S.). 2 patients (1 in Arm A and 1 in Arm B) developed Renal Failure.

**Conclusions:** Safety analysis allows study progression. Overall the only significant difference between the two arms was G 3–4 neutropenia. The excess of neutropenia in Arm A is entirely due to the induction phase.

### Table: G01*

<table>
<thead>
<tr>
<th>Neutropenia Grade 0-2</th>
<th>Grade 3-4</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARM A</td>
<td>67</td>
<td>18</td>
</tr>
<tr>
<td>ARM B</td>
<td>78</td>
<td>7</td>
</tr>
</tbody>
</table>

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