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## Two year results of clinical efficacy of cisplatin in combination with sodium thiosulfate (STS) vs. cisplatin alone in a randomized phase III trial for standard risk hepatoblastoma (SR-HB) SIOPEL 6

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**Background:** A serious permanent side effect of cisplatin (Cis) therapy is bilateral high-frequency hearing loss which is particularly debilitating when it occurs at a young age. Sodium thiosulfate (STS) has been shown to dramatically reduce hearing loss in children treated with cisplatin containing chemotherapy without tumor protection in localized disease.

**Methods:** Newly diagnosed SR-HB patients were randomized to Cis or Cis+STS for 4 preop and 2 postop courses. Cis 80mg/m<sup>2</sup> was administered over 6 hrs. STS was administered exactly 6 hours after stop Cis over 15 minutes at 20 g/m<sup>2</sup>. Tumor response was assessed after 2 and 4 cycles preop with serum AFP and liver imaging. In case of progressive disease STS was to be stopped and chemotherapy changed to combination therapy with Cis and doxorubicin 60mg/m<sup>2</sup>. The primary endpoint of the trial is centrally reviewed absolute hearing threshold, at the age of ≥3.5 years, by pure tone audiometry. Secondary endpoints are event free (EFS) and overall survival (OS).

**Results:** 109 patients (52 Cis and 57 Cis+STS) were recruited at trial closure in December 2014. The combination of Cis+STS was generally well tolerated. The median follow up is 32 months and provisional 2 years EFS is Cis 86.3% and Cis+STS 89.0%; 2 years OS is Cis 91.4% and Cis+STS 97.7%. Treatment failure defined as PD at 4 cycles was equivalent in both arms (3 Cis; 3 Cis+STS). As of February 2016, 5 patients had died (4 Cis; 1 Cis+STS), 1 had relapsed (Cis+STS) and 1 was still in PR (Cis+STS). Interim results of centrally reviewed and Brock graded audiograms for 68 patients at age >3.5yrs are encouraging. Definitive results will become available end 2017.

**Conclusion:** This randomized phase III trial in standard risk hepatoblastoma of cisplatin alone vs. cisplatin plus the otoprotectant STS shows comparable 2 years EFS and OS with no evidence of tumor protection.

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