732 Oncofid-P-B (paclitaxel-hyaluronic acid) in the intravesical therapy of patients affected by primary or recurrent Ta G1-G2 papillary cancer of the bladder. A phase II marker lesion study

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Introduction & Objectives: The standard of care for papillary non–muscle-invasive bladder cancer (NMIBC) is transurethral resection, followed by intravescical instillation with chemo- or immunotherapy to prevent recurrences. BCG or mitomycin C are the options of choice, although limited efficacy and high frequency of side effects is being constantly reported with both approaches. The primary objective of the present study was to assess the ablative activity of intravesical administration of Paclitaxel-hyaluronic acid solution (Oncofid-P-B 600 mg) on a multiple primary or recurrent Ta G1-G2 papillary tumor, adopting the “marker lesion” approach. The secondary objectives were: To evaluate time to relapse after Oncofid-P-B instillation during the maintenance phase; to determine number and percentage of patients with relapse at final visit; to evaluate the safety profile of Oncofid-P-B given by intravesical instillation.

Materials & Methods: This was a phase II, open-label, non-randomised, multicentre, international study with a first 6 weeks treatment phase followed by a 6+6 months maintenance phase. A total of 101 patients were screened in 14 sites localized in Germany (3), Italy (5) and Spain (6). 60 patients constituted the safety population (SP) and 52 patients the per protocol population (PP).

Results: The rate of complete response (CR) after 6 weekly instillations of Oncofid-P-B was of 45.0% (27 CR/60 patients) in the SP and 46.2% (24/52) in the PP population. CR rate was higher for the subset of patients who had not previously been treated with any chemo/immunotherapy (16/28 - 57.1% in the SP and 15/25 – 60.0% in the PP). A total of 12 (50.0%) out of the 24 patients included in the maintenance phase had a relapse, for these patients the median time to relapse from the first study drug administration was 15.70 months (95% CI: 9.9). Regarding recurrence-free survival of the patients in maintenance phase, the probability to be free of recurrence after 3, 6, 9 and 12 months from the first study drug administration was of 98.2%, 96.4%, 74.4% and 58.9%, respectively. One case of death reported during the study was considered as not related

to the study medication. Eight serious adverse events were reported in 6 patients, but only one (urinary tract infection) was considered drug related and resolved 5 days after treatment with antibiotics. None of the adverse events led to study discontinuation.

Conclusions: CR in patients with NMIBC (Ta-G1-G2) was observed in 45% of the patients treated with 6 weekly intravesical administration of Oncofid-P-B with a very good tolerability and safety profile. Higher rate of CR (57.1% in the SP and 60.0% in the PP) was reported in patients who were not previously treated with chemo/immunotherapy.