COMPLETE RESPONSE INDUCED BY 4413 NAMODENOSON, AN A3 ADENOSINE RECEPTOR AGONIST, IN A PATIENT WITH ADVANCED HEPATOCELLULAR CARCINOMA

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Background: No established treatments for patients with advanced hepatocellular carcinoma (HCC) and moderate hepatic dysfunction (Child-Pugh B; CPB) are currently available. A recent randomized placebo-controlled phase 2 clinical trial investigating namodenoson in patients with HCC and CPB demonstrated a favorable safety profile for namodenoson. The primary overall survival endpoint of this study was not met; however, namodenoson was associated with a significant improvement in 12-month overall survival (44% versus 18%, p = 0.028) in the subgroup of patients with CPB score of 7 (CPB7). A phase 3 trial in HCC CPB7 patients is ongoing. **Methods:** This case report describes a patient who participated in the phase 2 study of namodenoson vs placebo in CPB HCC. **Results:** A 61-year-old woman with HCC and CPB7 participated in the phase 2 study and had Barcelona Clinic Liver Cancer (BCLC) stage C and Eastern Cooperative Oncology Group performance status of 2 at baseline. The patient was in the namodenoson arm and continued treatment with namodenoson for 5 years under an open label extension program (treatment is ongoing). Alanine transaminase (ALT) and aspartate aminotransferase (AST) levels were elevated at baseline (68 U/L and 44 U/L, respectively), and normalized after 1 treatment cycle, Normal ALT and AST levels were maintained for 5 years. The serum α-fetoprotein level was 47 ng/ml at baseline, declined to normal levels after 5 cycles of treatment, and reached 1.3 ng/mL at time of complete response. At baseline, computed tomography (CT) scans demonstrated a large HCC tumor in the context of multifocal disease at baseline. Two treatment cycles later (e.g., after approximately 7 weeks) CT demonstrated shrinkage of the tumor mass that was consistent with a partial response. Within 4 years of treatment, disappearance of the tumor mass, ascites and peritoneal carcinomatosis was observed consistent with a complete response by RECIST 1.1 and mRECIST (Figure). No treatment-emergent adverse events were reported. At the time of reporting this case (5 years from treatment initiation), the response is ongoing as indicated by evaluation of liver functions and imaging studies. **Conclusion:** This case report demonstrates that treatment with namodenoson can lead to a complete and durable response in patients with HCC and CPB7. Figure: CT images of the tumor at baseline as well as 7 weeks and approximately 5 years after treatment initiation

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