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961MO Safety, efficacy, immunogenicity of arenavirus-based vectors HB-201 and HB-202 in patients with HPV16+ cancers

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Background: Human papillomavirus 16 positive (HPV16+) cancers are caused by stable expression of HPV16-specific E7 and E6 oncoproteins, also a source of highly immunogenic neoantigens. Reporting on the OPTIMAL vaccine program (HB-201/HB-202) intravenously (IV) with or without 1 intratumoral dose (IT) in HPV16+ cancers. Safety, tolerability, and preliminary anti-tumour activity by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 or immune RECIST were evaluated, as well as immunogenicity and pharmacodynamic biomarkers in blood and tissue tumour samples.

Results: The study treated 38 patients (29 with ≥1 efficacy scan) with confirmed HPV16+ cancers with a median (range) of 3 (1–10) prior antitumor therapies. The most common primary cancer site was oropharynx (76%), followed by cervical (7.9%). HPV16+ cancers with a median (range) of 3 (1–7) prior antitumor therapies. The most common primary cancer site was oropharynx (76%), followed by cervical (7.9%). Among 33 evaluable patients who received HB-201, 5 (15%) had SD, 2 (6%) had CR, 2 (6%) had PR, 2 (6%) had NR, and 20 (61%) had PD. Among 31 evaluable patients who received HB-202, 3 (10%) had SD, 2 (6%) had CR, 1 (3%) had PR, 1 (3%) had NR, and 24 (78%) had PD. Among 34 evaluable patients who received HB-201/HB-202, 7 (21%) had SD, 6 (18%) had CR, 4 (12%) had PR, 2 (6%) had NR, and 21 (62%) had PD. Among 25 evaluable patients who received HB-201/HB-202, 4 (16%) had SD, 4 (16%) had CR, 5 (20%) had PR, 3 (12%) had NR, and 14 (56%) had PD. Among 19 evaluable patients who received HB-201/HB-202, 3 (16%) had SD, 1 (6%) had CR, 1 (6%) had PR, 1 (6%) had NR, and 14 (74%) had PD. Among 15 evaluable patients who received HB-201/HB-202, 2 (13%) had SD, 2 (13%) had CR, 2 (13%) had PR, 1 (7%) had NR, and 10 (67%) had PD. Among 14 evaluable patients who received HB-201/HB-202, 2 (14%) had SD, 1 (7%) had CR, 2 (14%) had PR, 1 (7%) had NR, and 10 (71%) had PD. Among 11 evaluable patients who received HB-201/HB-202, 1 (9%) had SD, 1 (9%) had CR, 2 (18%) had PR, 1 (9%) had NR, and 8 (73%) had PD. Among 10 evaluable patients who received HB-201/HB-202, 1 (10%) had SD, 1 (10%) had CR, 2 (20%) had PR, 1 (10%) had NR, and 7 (70%) had PD. Among 9 evaluable patients who received HB-201/HB-202, 1 (11%) had SD, 1 (11%) had CR, 2 (22%) had PR, 1 (11%) had NR, and 6 (67%) had PD. Among 8 evaluable patients who received HB-201/HB-202, 1 (13%) had SD, 1 (13%) had CR, 2 (25%) had PR, 1 (13%) had NR, and 5 (63%) had PD. Among 7 evaluable patients who received HB-201/HB-202, 1 (14%) had SD, 1 (14%) had CR, 2 (29%) had PR, 1 (14%) had NR, and 4 (57%) had PD. Among 6 evaluable patients who received HB-201/HB-202, 1 (17%) had SD, 1 (17%) had CR, 2 (33%) had PR, 1 (17%) had NR, and 3 (50%) had PD. Among 5 evaluable patients who received HB-201/HB-202, 1 (20%) had SD, 1 (20%) had CR, 2 (40%) had PR, 1 (20%) had NR, and 2 (40%) had PD. Among 4 evaluable patients who received HB-201/HB-202, 1 (25%) had SD, 1 (25%) had CR, 2 (50%) had PR, 1 (25%) had NR, and 1 (25%) had PD. Among 3 evaluable patients who received HB-201/HB-202, 1 (33%) had SD, 1 (33%) had CR, 2 (67%) had PR, 1 (33%) had NR, and 2 (67%) had PD. Among 2 evaluable patients who received HB-201/HB-202, 1 (50%) had SD, 1 (50%) had CR, 2 (100%) had PR, 1 (50%) had NR, and 1 (50%) had PD. Among 1 evaluable patient who received HB-201/HB-202, 1 (100%) had SD, 1 (100%) had CR, 2 (100%) had PR, 1 (100%) had NR, and 1 (100%) had PD.
A phase I clinical trial on intratumoral injection of autologous CD1c (BCDA-1)+/CD141 (BCDA-3)+ myeloid dendritic cells (mDCs) in combination with talimogene laherparepvec (T-VEC) in patients with advanced pretreated melanoma


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Background: Intratumoral (IT) myDC play a pivotal role in initiating antitumor immune response (IR). Sensing of tumor neoantigens by T cells is a prerequisite for effective anticancer T-VAC may lead to the release of tumor antigens and maturation signals that can be captured and processed by CD1c (BCDA-1)+/CD141 (BCDA-3)+ myDC, thereby reinvigorating the cancer immune cycle. Patients (pts) with ICI-refractory melanoma received IT injections of the oncolytic virus T-VAC may processed by CD1c (BCDA-1)+/CD141 (BCDA-3)+ myDC, thereby reinvigorating the cancer immune cycle. Methods: Patients (pts) with ICI-refractory melanoma received IT injections of the oncolytic virus T-VAC may processed by CD1c (BCDA-1)+/CD141 (BCDA-3)+ myDC, thereby reinvigorating the cancer immune cycle. Results: 13 pts were enrolled (C1: n=7; respectively 2, 2, and 3 pts per dose-level of CD1c (BCDA-1)+/CD141 (BCDA-3)+ myDC, thereby reinvigorating the cancer immune cycle. Patients (pts) with ICI-refractory melanoma received IT injections of the oncolytic virus T-VAC may processed by CD1c (BCDA-1)+/CD141 (BCDA-3)+ myDC, thereby reinvigorating the cancer immune cycle. Conclusions: IT co-injection of CD1c (BCDA-1)+/CD141 (BCDA-3)+ myDC plus T-VAC is feasible, tolerable, and resulted in encouraging early signs of durable antitumor activity in pts with ICI-refractory melanoma. Clinical trial identification: NCT03747744.