956 RETIFANLIMAB (INCMGA00012) IN PATIENTS WITH RECURRENT MSI-H OR DMMR ENDOMETRIAL CANCER: RESULTS FROM THE POD1UM-101 STUDY

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Background Management of patients with recurrent endometrial cancer after failure on platinum-based therapy remains a clinical challenge. Retifanlimab (INCMGA00012) is an investigational humanized immunoglobulin G4 monoclonal antibody against programmed cell death 1 (PD-1). We previously reported encouraging results from a preplanned interim analysis in patients with microsatellite instability-high (MSI-H) recurrent endometrial cancer treated with retifanlimab in POD1UM-101 [1]. Here, we provide top-line results from the full cohort of patients in the POD1UM-101 study.

Methods Eligible patients have histologically proven, unresectable recurrent MSI-H or deficient mismatch repair (dMMR) endometrial cancer (per local testing), ECOG PS ≤1, disease progression during or following 1 to ≤5 prior systemic treatments, measurable disease (per RECIST v1.1), and are naïve to prior immune checkpoint inhibitors. MSI-H and dMMR status were centrally confirmed using PCR and IHC, respectively. Patients receive retifanlimab 500 mg every 4 weeks for up to 2 years. The primary study endpoint is safety. Confirmed best overall response and duration of response (DOR) were evaluated by independent central review (ICR) using RECIST v1.1.

Results As of July 6, 2021, 76 patients with centrally confirmed MSI-H (65 [85.5%]) or dMMR (11 [14.5%]) endometrial cancer had received ≥1 dose of retifanlimab; median age was 67.0 (49–88) years, 70 (92.1%) had endometrioid histology, 67 (88.2%) had metastatic disease, and 61 (80.3%) had visceral metastases. Sixty-eight (89.5%) patients had prior surgery or procedure, 54 (71.1%) patients were treated with radiotherapy, and 75 (98.7%) patients had received prior systemic therapy for advanced disease (33 [43.4%] received ≥2 prior systemic therapies for advanced disease). Median retifanlimab exposure was 7.4 (0.03–23.0) months. At data cutoff, 2 (2.6%) patients completed treatment and 30 (39.5%) were on treatment. Grade ≥3 treatment emergent AEs (TEAEs) occurred in 33 (43.4%) patients, including 10 (13.2%) with anemia and 7 (9.2%) with an immune-related AE (nephritis, n=2; autoimmune hepatitis, hepatitis, myositis, rash, and pneumonitis, n=1 each). There were no treatment-related AEs with fatal outcome. Centrally confirmed objective responses were observed in 33 (43.4%) patients (95% CI, 32.1–55.3), with 11 (14.5%) complete and 22 (28.9%) partial responses. Of the 33 patients with objective response, 25 (75.8%) had DOR for ≥6 months; median DOR was not reached. Median follow-up time for response was 8.4 (range, 1.9–28.3) months.

Conclusions Retifanlimab was well tolerated and demonstrated encouraging antitumor activity in patients with pretreated recurrent MSI-H or dMMR endometrial cancer, consistent with that achieved with other PD-1 therapies.

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Trial Registration ClinicalTrials.gov NCT03059823, EudraCT 2017-000865-63

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Ethics Approval This study was approved by institutional review boards or independent ethics committees in Belgium (Aan de Commissie Medische Ethiek University Hospitals Leuven [CEC: S62335]; Ethics Committee of Hospital-Faculty University of Liège [LEC: 2019/48]); Bulgaria (Ethics Committee for Clinical Trials, Sofia [RA: IAL-24443/08.06.2017; CEC: □□-80/08.06.2017]); Finland (HUS Tutkimuseettiset toimikunnat Biomedicum Helsinki [RA: KLnro 124/2019]); France (CPP Île-de-France X Hôpital, Aulnay-sous-Bois cedex [RA: MED MSA NAT-2019-08-00080; CEC: CN-RIPH 19.02.17.56415/CPP 27-2019]); Germany (Ethik-Kommission der Albert-Ludwigs-Universität Freiburg, Freiburg [RA: 3102/012; EC: 506/18]; Ethics Committee at the Technical University of Dresden, Dresden [RA: 3102/012; EC: EK 4854 AB]; Ethics Committee of the State of Berlin, Berlin [RA: 3102/012; EC: 17/0411 EK 12/15]); Italy (Comitato Etico del Policlinico Gemelli Fondazione Policlinico Universitario "Agostino Gemelli", Roma (RM) [no approval number issued by RA or EC]; Comitato Etico IRCCS di Candiolo, Candiolo-TO [no approval number issued by RA or EC]); Latvia (Ethics Committee for Clinical Research at Development Society of Pauls Stradins Clinical University Hospital, Riga [no approval number issued by RA or EC]); Lithuania (Lithuanian Bioethics Committee, Vilnius [no approval number issued by RA or EC]); Poland (Komisja Bioetyczna przy Uniwersytecie Medycznym, Pozna□ [RA: UR.DBL.474.0350.2017; CEC: 622/17]); Spain (Comité de Ética de Investigación con Medicamentos, Madrid Centro Actividades Ambulatoria [RA: 17-073 (Locator: 2VK42NE57D); CEC: 17/211]); Ukraine (Ethical Committee at Prykarpatsky Regional Clinical Oncology Center of Ivano-Frankivsk Regional Rada, Ivano-Frankivsk [no approval number issued by RA or EC]); United States (IntegReview IRB, Austin, TX [no approval number issued by IRB]; The University of Texas MD Anderson Cancer Center Institutional Review Board, Houston, TX [no approval number issued by IRB]).

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