TPS4236 Poster Session

IMMUNORARE[5]: A national platform of 5 academic phase II trials coordinated by Lyon University Hospital to assess the safety and the efficacy of the immunotherapy with domvanalimab + zimberelimab combination in patients with advanced rare cancers—The Peritoneal Mesotheliomas Cohort.

Julien Peron Sr., Valerie Boige, Pascale Mariani, Clarisse Eveno, Denis Michel Smith, Laurence Gladieff, Judith Raimbourg, Nicolas Pirro, Julien Edeline, Marie Viala, Cecile Brigand, Cecile Vicier, Pascale Tomasini, Diego Tosi, Sara Calattini, Sylvie Bin, Fabien Subtil, Benoit You, Vahan Kepenekian; Centre Hospitalier Lyon Sud - Hospices Civils de Lyon, Pierre-Bénite, France; Institut Gustave Roussy, Villejuif, France; Eugene Marquis, Paris, France; CHRU of Lille, Lille, France; Centre Hospitalier Universitaire de Bordeaux, Groupe Hospitalier Sud, Hopital Haut-Leveque, Pessac, France; Oncopole Claudius Regaud IUCT-Oncopole, Toulouse, France; Insitut de Cancérologie de l'Óuest, Saint-Herblain, France; Assistance Publique Hopitaux de Marseilles, Marseille, France; Eugène Marquis Center, Rennes, France; Institut du Cancer de Montpellier, ICM, Montpellier, France; CHU Hautepierre, Strasbourg, France; Institut Paoli-Calmettes, Marseille, France; Assistance Publique des Hopitaux de Marseille, Marseille, France; Institut régional du Cancer de Montpellier (ICM), Head, Early Clinical Trial Unit, Medical Oncology Departement, Inserm U1194, Montpellier University, Montpellier, France; Hospices Civils de Lyon Cancer Institute, Oullins - Pierre-Benite, France; Pôle Santé Publique, Hospices Civils de Lyon, Lyon, France; Service de biostatistique bioinformatique – Hospices Civils de Lyon, Lyon, France; Centre Hospitalier Universitaire Lyon Sud, Hospices Civils de Lyon, Oullins-Pierre-Bénite, France; Centre Hospitalier Lyon Sud, EMR 3738 Université Claude Bernard Lyon 1, Lyon, France

Background: In patients with rare cancers, there is an unmet medical need for investigating innovative therapeutics beyond standard first-line treatment. Indeed, these diseases are rarely assessed in clinical trials. The standard 1st-line treatment of peritoneal mesothelioma relies on platinum and pemetrexed, with no validated 2nd-line treatment so far. Several studies suggested that immunotherapy, such as ipilimumab + nivolumab or atezolizumab + bevacizumab, is active in this disease. There is a strong biological rationale for concurrent blockage of TIGIT and PD1 pathways in mesothelioma. **Methods:** IMMUNORARE[5] (NCT06790706) is a platform of 5 single arm phase II trials testing the safety and the efficacy of DOMVANALIMAB (anti-TIGIT) and ZIMBERELIMAB (anti PD-1) in 5 independent cohorts of rare cancers. The trial, sponsored by Lyon University Hospital, is conducted in 15 French centers, in partnership with the corresponding national networks of reference centers. The PERITONEAL MESOTHELIOMA cohort, led in collaboration with the RENAPE network (https://www.renape-online.fr/), will enroll 27 patients in progression after at least 1 line of platinum + pemetrexed based-chemotherapy regimen, with evaluable lesions at the baseline (modified RECIST criteria). Patients previously treated with immunotherapy will not be eligible. Patients will receive intra-venous DOMVANALIMAB and ZIMBERELIMAB, every three weeks, until disease progression. The primary endpoint will be the progression-free survival rate at 6 months. The disease progression (clinical or radiological) will be confirmed by the RENAPE experts. The secondary endpoints are tolerance, overall response rate and duration of response, progression-free and overall survival. A two-stage Simon design was used, with early termination rules for futility (5% one-sided alpha level, 80% power). The treatment would be considered interesting if the percentage of patients free from disease progression at 6-months is statistically higher than 35%; 60% is expected. Translational research projects will be developed aiming at deciphering cellular and molecular mechanisms involved in response to treatment. Moreover, data from the prospectively-maintained RENAPE database will be investigated to build a synthetic historical arm representative of the efficacy of the standard treatments in a similar population of patients. Clinical trial information: NCT06790706. Research Sponsor: GILEAD.