TPS8130 **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 B3 Thymomas and Thymic Carcinomas Cohort.

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Background: In patients with rare cancers, there is an unmet medical need for investigating innovative therapeutics. Indeed, these diseases are rarely assessed in clinical trials. Thymic epithelial tumors (TET) are rare heterogeneous thoracic malignancies. B3 TET and thymic carcinomas are more aggressive and prone to metastatic spreading. The standard 1st line treatment relies on platinum-based chemotherapy. Consensual 2nd line treatment has not been identified yet. Several studies showed limited efficacy of PD-1 blockade in B3 TET and thymic carcinomas. Concurrent blockage of TIGIT and PD-1 immune checkpoint B3 TET may improve outcomes according to translational studies. **Methods:** IMMUNORARE^{5} (NCT06790706) is a platform of 5 single arm phase II trials testing the safety and 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 French national reference centers. The B3 TET and thymic carcinomas cohort, led in collaboration with the RYTHMIC Network (www.rythmic.org), will enroll 26 patients after failure of at least one line of platinum-based chemotherapy, with evaluable lesions at baseline according to RECIST criteria. Patients previously treated with immunotherapy are not eligible. Patients will receive Domvanalimab and Zimberelimab intravenous, every three weeks, until disease progression or unacceptable toxicity. The primary endpoint is the progression-free survival rate at 6 months. The secondary endpoints are overall response rate and duration of the response, progression-free survival, overall survival and tolerability. The trial is designed with a two-stage Simon design, with early termination 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 40%; 65% is expected. Translational research projects will be developed aiming at deciphering cellular and molecular mechanisms involved in response to treatment. Moreover, data from the prospective database of the RYTHMIC network 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.