Background and importance The introduction of biological drugs changed the pharmaceutical market, improving patients' prognoses and quality of life. Intravenous MabThera, authorised in January 1998, is the originator of the monoclonal antibody rituximab. In Italy, the regulatory agency approved the first rituximab biosimilar, Truxima, in July 2014, and the second, Rixathon, in December 2017.

Aim and objectives The objective was to analyse and compare MabThera and its biosimilars in our region in the period 2017–2019 in terms of regional consumption, costs and adverse drug reactions (ADRs).

Material and methods Regional consumption and costs data for rituximab between January and September 2017, 2018 and 2019 were collected and analysed, using Microsoft. ADR reports were extracted from the Adverse Drug Reactions National Report (ADRsNR) and stratified by gravity, gender of the patient and diagnosis.

Results In 2017, the number of intravenous MabThera dispensed packs was 10 017, with a progressive reduction over the years (552 in 2019). Truxima decreased from 2274 delivered packs in 2018 to 117 in 2019; Rixathon increased from 3491 in 2018 to 9259 in 2019. Intravenous distributed pack numbers of MabThera decreased from 2017 to 2019 and was about –94.49%. Regarding costs, MabThera expenditure in 2017 was about 9 902 232.64€, in 2018 it was 3 590 428.00€ and in 2019 it was 613 502.88€. Truxima costs were 2 027 695.38€ in 2018 and 91 438.67€ in 2019. Rixathon expenditure was 2 066 974.79€ in 2018 and 5 473 728.71€ in 2019. A reduction of 93.80% was registered for MabThera expenditure from 2017 to 2019. From January 2002 to March 2020, ADRsNR rituximab ADRs were 2865: 10.23% MabThera, 19.02% Truxima and 10.66% Rixathon. 50.3% of patients were men and 49.7% women. ADR gravity was 2.2% deaths, 39.1% serious and 57.8% not serious. Diagnoses principally concerned itch 7.9%, dyspnoea 7%, neutropenia 7.3% and pyrexia 7%.

Conclusion and relevance ADRsNR biosimilar data are still limited: greater collaboration between health professionals is needed to structure a system of more robust and adequate pharmacovigilance, to overcome the information gap relating to the security of the originator and biosimilar. Nonetheless, biosimilar drugs are a valid therapeutic alternative for patients, and a good way to reduce expenditure and to optimise available resources, ensuring good pharmaceutical governance. Biosimilar switch involves a multidisciplinary team composed by prescribers and pharmacists. Pharmacovigilance is important to discover and characterise ADRs in the post-marketing phase.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-158 OFF-LABEL USE OF PEMBROLIZUMAB IN PD-L1 POSITIVE METASTATIC ANAPLASTIC THYROID CARCINOMA: A CASE REPORT

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Background and importance Anaplastic thyroid carcinoma (ATC) is a rare aggressive carcinoma representing 1–2% of all thyroid carcinomas. For patients with metastatic ATC, systemic

chemotherapy with taxanes, platinum compounds or adriamycin is recommended. Several studies have shown that BRAF mutated tumours have higher expression of programmed death ligand 1 (PD-L1) (82%) compared with BRAF wild-type tumours (13%). For patients with metastatic ATC, systemic chemotherapy with taxanes, platinum compounds or adriamycin is recommended.

Aim and objectives To describe the clinical case of a 38-year-old man with BRAF negative and PD-L1 positive metastatic ATC, treated with pembrolizumab. This drug is not indicated for ATC treatment but its off-label use in combination with lenvatinib is justified by one study¹ and a few case reports.^{2 3}

Material and methods At the end of 2019, the patient presented with paraesthesia and slight swelling in the mandibular, and in March 2020 a progressive increase in the volume of the lesion was observed. From March to April 2020, evaluations were carried and multifocal infiltrations in the mandible, thyroid, liver, lungs, bones, bone marrow and vena cava inferior were observed. Blood tests (thyroglobulin value was 6468 ng/mL) and thyroid biopsy were performed and the results confirmed the diagnosis of metastatic ATC. Because of the spread of the metastases and the speed of development of carcinoma, radiotherapy and surgery were not indicated. Therefore, the patient was treated with paclitaxel 80 mg/m² once a week combined with lenvatinib 14 mg/day. Metastatic progression was observed by CT after 20 days. Treatment with pembrolizumab 200 mg every 3 weeks combined with lenvatinib 14 mg/day was started.

Results After 3 months from the start of pembrolizumab and after 14 weeks from the start of lenvatinib, a reduction in thyroglobulin was detected (4906 ng/mL) and the results of vertebral MR and mandibular CT showed a reduction in metastases. Currently, the treatment is ongoing (six doses administered) and is well tolerated.

Conclusion and relevance Pembrolizumab combined with lenvatinib seemed to be effective in treating metastatic ATC and could become a therapeutic choice for patients presenting with PD-L1 expression.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. <https://pubmed.ncbi.nlm.nih.gov/29996921/>
2. <https://pubmed.ncbi.nlm.nih.gov/31885948/>
3. <https://pubmed.ncbi.nlm.nih.gov/31637475/>

Conflict of interest No conflict of interest

5PSQ-159 PALBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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Background and importance Loss of cell cycle regulation due to pathway alterations in cyclin D-CDK4/6-Rb is common in breast cancer. Palbociclib is a CDK4/6 inhibitor, indicated in metastatic breast cancer (mBC).

Aim and objectives The aim of this study was to analyse the safety profile of patients with mBC positive hormone receptors receiving treatment with palbociclib.

Material and methods A retrospective descriptive study was conducted in patients with mBC receiving treatment with palbociclib from July 2019 to July 2020. Electronic prescription