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

SMA Giordano*, M Scaldaferri, E Caiazza, F Cattel. *Aou Città Della Salute E Della Scienza Di Torino-Italy, Hospital Pharmacy, Turin, Italy*

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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 study[1] 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/m^2 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

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Conflict of interest No conflict of interest

5PSQ-159 PALBOCICLIB SAFETY IN METASTATIC BREAST CANCER

FJ Salmeron Navas*, E Rios-Sanchez, M Dominguez Cantero, EM Barreiro-Fernandez. *Hospital Universitario Puerto Real, Servicio De Farmacia, Cadiz, Spain*

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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

programme for outpatient and medical records was consulted. Data collected for each patient were: sex, age, menopause status, performance status (PS), cancer stage, presence of visceral metastatic disease, therapeutic scheme and number of cycles received. The safety profile was assessed from the number of adverse events (AE), and the severity of AEs was graded on the basis of the common terminology criteria for adverse events, V.5.0. Number of patients and reasons for delays and dose reductions were also determined.

Results 34 patients, 100% women, were included, with an average age of 60 (47–81) years, of whom 71% were postmenopausal. 29 patients presented at the beginning of treatment with PS ≤1. The percentage of patients with metastatic disease was 100%, of whom 76% had visceral metastases. The schemes, average numbers and range of cycles were: palbociclib 125 mg every 3 weeks, 7 (1–17) cycles. 105 AE occurred in 31 patients (91%): 54 haematological, 23 metabolic, 10 digestive, 7 asthenia, 2 cases of infections and 9 other causes. The degree of severity was: anaemia, anorexia asthenia, diarrhoea, dysgeusia, increased levels of GGT/AST/ALT/LDH, mucositis, nausea, neutropenia, itching, palmar–plantar erythrodysaesthesia syndrome, thrombopenia, urticaria and vomiting, grade 1 (59%); anaemia, anorexia, asthenia, headaches, GGT increased, infections, mucositis, nausea, neutropenia and vomiting, grade 2 (30%); and asthenia, neutropenia and GGT increased, grade 3 (12%). There were 13 patients who delayed treatment, and neutropenia was the reason in 85% of patients. 6% of patients had reduced doses of palbociclib because of neutropenia or mucositis.

Conclusion and relevance There was a high incidence of AE, the most frequent being grade 1. The most common AE were haematological, with neutropenia being the highest degree. Our studies suggested a high percentage of delays and dose reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-160 MOGAMULIZUMAB EXPERIENCE IN ADVANCED SEZARY SYNDROME: A CASE REPORT

A Ganfornina Andrades*, C Rodriguez Moreta, M Corrales Paz, I Lomares Manzano, MJ Martinez Bautista. *Puerta Del Mar University Hospital, Pharmacy, Cádiz, Spain*

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Background and importance Sezary syndrome (SS) is a primary cutaneous T cell lymphoma characterised by erythroderma, lymphadenopathy and leukaemic involvement of the peripheral blood. The high relapse rates and poor prognosis complicate its clinical course and treatment. Mogamulizumab is an anti-CC chemokine receptor 4 monoclonal antibody that has been recently approved for the treatment of adult patients with relapsed or refractory mycosis fungoides or SS who have been treated with at least one prior line of therapy.

Aim and objectives To describe the use of mogamulizumab in a patient with SS as well as the safety of this new treatment.

Material and methods We ran a descriptive study of SS in a 77-year-old woman with erythema for 8 years. Skin lesions were widely distributed over 80% of her body. The patient was initially diagnosed with contact dermatitis and then psoriasis. She received various treatments without success: antihistamines, topical corticosteroids, acitretin, cyclosporine, oral prednisone, phototherapy, ustekinumab, ixekizumab, methotrexate and bexarotene. In June 2020, due to new recurrences, additional skin biopsy and study of bone marrow were done to determine the specific type of skin lesions. Stage IV SS (pT4pM0pN0 B2) was diagnosed, and physicians decided to start expanded access treatment with mogamulizumab.

Results The patient received eight doses (80 mg/dose) of mogamulizumab from June to October 2020. It was administered with the approved protocol: 1 mg/kg dose, as an intravenous infusion over at least 60 minutes, on days 1, 8, 15, and 22 of the first 28 day cycle, then on days 1 and 15 of each subsequent 28 day cycle until disease progression or unacceptable toxicity. The woman presented good clinical evolution with reduction of skin lesions and symptoms. The treatment was well tolerated, with few reported adverse side effects: low grade fever after the first infusion and grade IV afebrile neutropenia after the sixth dose. Severe neutropenia was successfully treated with granulocyte colony stimulating factors and the patient was able to continue treatment.

Conclusion and relevance Mogamulizumab was used successfully to date in our case. Although more and longer treatment periods are needed, mogamulizumab seems to be a well tolerated treatment option for SS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-161 EFFECTIVENESS AND SAFETY OF PALBOCICLIB AND RIBOCICLIB

FJ Alonso Zazo*, M Moreno-Garcia, F Fernandez-Fraga, R Diez-Fernandez, T Molina-Garcia. *Hospital Universitario Getafe, Servicio Farmacia Hospitalaria, Getafe, Spain*

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Background and importance Several trials have demonstrated the benefit of anti-CDK4/6 inhibitors plus endocrine therapy in oestrogen receptor positive (ER+) advanced breast cancer (aBC), in first or subsequent lines of therapy. Based on clinical trials, palbociclib and ribociclib are equally effective in either firstline or secondline therapy for advanced ER+ aBC, however, different toxicity profiles have been reported.

Aim and objectives To assess progression free survival (PFS) and safety of palbociclib and ribociclib in real clinical practice.

Material and methods An observational, retrospective, descriptive study was conducted in patients with aBC treated with palbociclib and ribociclib between February 2018 and September 2020. Age, doses, adverse events, time to progression or death, and medical history were collected.

Results 42 patients were included (24 received palbociclib and 18 received ribociclib). Ribociclib: mean age at the start of treatment was 58.94±11.79 years. 16.67% of patients withdrew their treatment due to toxicity. 16.67% progressed (PFS of 9.9±5.07 months). Patients began with doses of 600 mg: almost 40% of patients had to reduce the dose, of whom 28.57% had to reduce it to the minimum dose of 200 mg and the rest maintained on the 400 mg dose.

Palbociclib mean age at the start of treatment was 59.37 ±10.74 years. There were only two cases of toxicity (8.33%). 45.83% of patients progressed (PFS of 7.81±6.26 months). Patients started with a dose of 125 mg: 58.33% of patients