

5PSQ-064 INTENSIVE MONITORING OF AFATINIB – CASE REPORT

AS Santos*, M Lobo Alves, P Cavaco, E Viegas, F Falcão. *Hospital de São Francisco Xavier – Centro Hospitalar de Lisboa Ocidental, Pharmacy, Restelo, Portugal*

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Background The implementation of intensive monitoring programmes allows the identification of early occurrence of adverse drug reactions (ADR), in a comprehensive and exhaustive way. Afatinib was included in this pharmacovigilance programme (PP), which involves patient follow-up, carried out by pharmacists, to monitor the safety use of new drugs.

Purpose Analyse the results of afatinib in a PP.

Material and methods A retrospective study was carried out to analyse the follow-ups of a patient treated with afatinib. Data were collected by consulting the patient's clinical file and monitoring records of the pharmaceutical department.

Results Female patient, 88 years' old, caucasian with non-small cell lung cancer, with pleural metastasis and EGFR+. Started first-line treatment in December 2016 with oral vinorelbine, suspended in April 2017 due to gastrointestinal intolerance. Started afatinib 40 mg in April 2017 and was included in the PP. First follow-up performed by the pharmacist in May, patient showed erythematous/acneiform skin reaction dispersed in limbs and trunk, intense pruritus, nausea and ocular complaints. Pharmacist advised the oncologist and it was decided to oversight. Eye complaints continued in the second follow-up in June. The oncologist was called again, evaluated and referred the patient to ophthalmology. The patient was observed in July and diagnosed with keratitis with ulceration in the left eye, which led to the suspension of treatment in August. The patient resumed treatment with dose reduction (afatinib 30 mg) in November, with improvement of complaints. In the March 2018 follow-up, the patient referred to the pharmacist numbness, rash and face oedema. The oncologist was called and decided to maintain therapy and oversight. In the next follow-up the patient maintained the complaints and treatment was suspended. Both suspected ADR were reported to the national pharmacovigilance unit. An imaging control of the disease was programmed to further decisions concerning treatment. In July, there was evidence of biochemical progression, and the oncologist discontinued therapy.

Conclusion The early approval of drugs that covers therapeutic gaps reveals the necessity to implement effective and systematic methodologies that allow the surveillance of their use. Monitoring by the pharmacist promotes and contributes to safety and adherence in the use of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

<http://www.ema.europa.eu>

No conflict of interest.

5PSQ-065 MANIC SYMPTOMATOLOGY INDUCED BY ALECTINIB: A CASE REPORT

¹L Zampogna*, ¹G Lo Cricchio, ¹L Gambitta, ¹E Togliardi, ¹L Ventura, ²A Grecchi, ³D Di Benedetto. ¹Asst Santi Paolo E Carlo, Ospedale San Carlo Borromeo- U.O. Farmacia, Milano, Italy; ²Asst Santi Paolo E Carlo, Ospedale San Carlo Borromeo- U.O. Psichiatria, Milano, Italy; ³Asst Santi Paolo E Carlo, Asst Santi Paolo E Carlo- U.O. Farmacia, Milano, Italy

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Background Alectinib is indicated as a second-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) anaplastic lymphoma kinase (ALK) positive, previously treated with crizotinib. Clinical safety data do not report adverse drug reactions (ADR) on the central nervous system. This drug is on the European list of medicinal products under additional monitoring.

Purpose Describe a case of manic episodes in a patient with advanced NSCLC treated with alectinib.

Material and methods Retrospective observation of a clinical case. The data – diagnostic tests, therapy and clinical course – were obtained by the review of medical records.

Results A 46 years' old female affected by NSCLC ALK positive with brain metastases began treatment with alectinib in December 2017. Treatment, four capsules twice a day, allowed cancer regression and metastasis disappearance. In March 2018, a CT scan with and without contrast agent (80 cc Ioversol 370 mg/mL), did not show pathological signs in intracranial space or grooves growth of the convexities. History was negative for psychiatric disorders but after the beginning of treatment, the patient developed an anxious depressive symptomatology and insomnia that worsened in the next months. Between February and May 2018, the patient was hospitalised four times at the Psychiatric Diagnosis and Treatment Service, and diagnosed with bipolar severe disorder: psychotic characteristics with persistently high mood, irritable and expanded, logorrhea, agitation, impairment of social functioning, delirium with ideas of grandeur and persecution. This ADR has been reported on the national pharmacovigilance network.

Psychotic symptoms were treated with Sodium Valproate 300 mg os, Aripiprazole 400 mg ev, Lithium Carbonate 300 mg os, and high doses of Lorazepam and Olanzapine up to 30 mg. The patient responded well but had recurrences after each hospital discharge. Although initially this could be supposed as poor treatment compliance, this was impossible due to long-acting injectable therapy with normal levels of valproataemia and lithaemia.

The patient continued the therapy with Olanzapine and Lorazepam.

Conclusion In the literature there are no cases of Alectinib neurological toxicity. For this reason, healthcare professionals need to monitor carefully any unexpected ADR that can manifest itself during treatment with new drugs, especially those under additional monitoring.

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Pubmed; Abstract book EJHP; RCP Alectinib and clinical studies; RNFV.

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5PSQ-066 THE OTHER SIDE OF IMMUNOTHERAPY: SAFETY AND TOXICITY MANAGEMENT IN CLINICAL PRACTICE

¹E Zhan Zhou*, ¹Mi Barcia Martin, ¹P Toro Chico, ²X Mielgo Rubio, ¹M Perez Encinas. ¹Hospital Universitario Fundación Alcorcón, Pharmacy Service, Alcorcón, Spain; ²Hospital Universitario Fundación Alcorcón, Medical Oncology Service, Alcorcón, Spain

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Background Nivolumab and Pembrolizumab are monoclonal antibodies that block the programmed-cell-death-ligand (PD-L1) and its receptor (PD-1) respectively, inhibiting the immune