OLARATUMAB: WHAT IS THE ECONOMIC IMPACT ON THE NATIONAL HEALTH SYSTEM?

C. Migliazzi[1], C. Della Costanza[2], E. Aliprandi[2], C. Tirone[2], M. Galassi[2], V. Ladisa[2]

[1] School of Specialization in Hospital Pharmacy - University of Milan, Pharmacological sciences, Milan, Italy.

[2] Fondazione IRCCS Istituto Nazionale dei Tumori, Pharmacy, Milan, Italy.

Contact: cecilia.migliazzi@unimi.it

Background and Importance

Food and Drug Administration (FDA) granted Olaratumab (human Anti-PDGFRα monoclonal antibody (**Fig. 1**)) fast-track authorisation in November 2016 to treat advanced Soft Tissue Sarcoma (STM) (1).

Also the European Medicines Agency (EMA) allowed then a conditional marketing authorisation for this drug after the phase 1b/2 trial. In the post-authorization phase III trial ANNOUNCE, of Olaratumab in combination with doxorubicina, data were limited for the small number of patients included and the lack of confirmation of efficacy and clinical benefit (2). Consequently, EMA banned the treatment of new patients with Olaratumab (3).

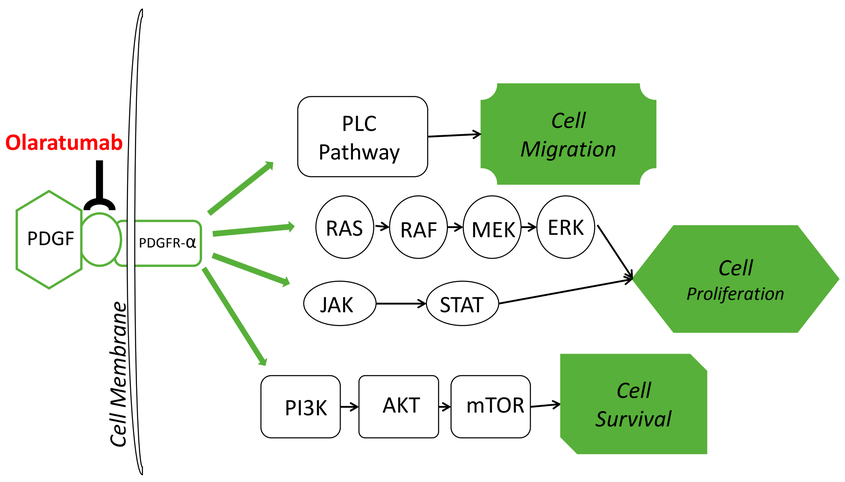

Fig. 1 Olaratumab Mechanism of Action (1).

Aim and Objectives

We studied the economic impact of Olaratumab on the the Italian national health service, for our hospital patients, from its introduction in our country (November 2017) to the EMA ban (January 2019).

https://www.eahp.eu/25-5PSQ-045

Abstract number: 5PSQ-045

ATC code: L01 – Cytostatics

Materials and Methods

A retrospective analysis was conducted. In our hospital 17 patients, 11 of which female (64.7%), with a mean age 54.7± 24.5 years, were treated with Olaratumab.

The data (weight and doses prescribed) were extracted from our chemotherapies' prescriptions and preparation database software. We selected patients treated by Olaratumab.

Results

A Olaratumab vial cost was € 1375. The recommended dose was 15mg/kg on days 1+8 of each 21-day cycle.

Between November 2017 and January 2019, in our hospital 17 patients completed 79 total cycles for a total cost of **€ 541750 (Fig. 2)**.

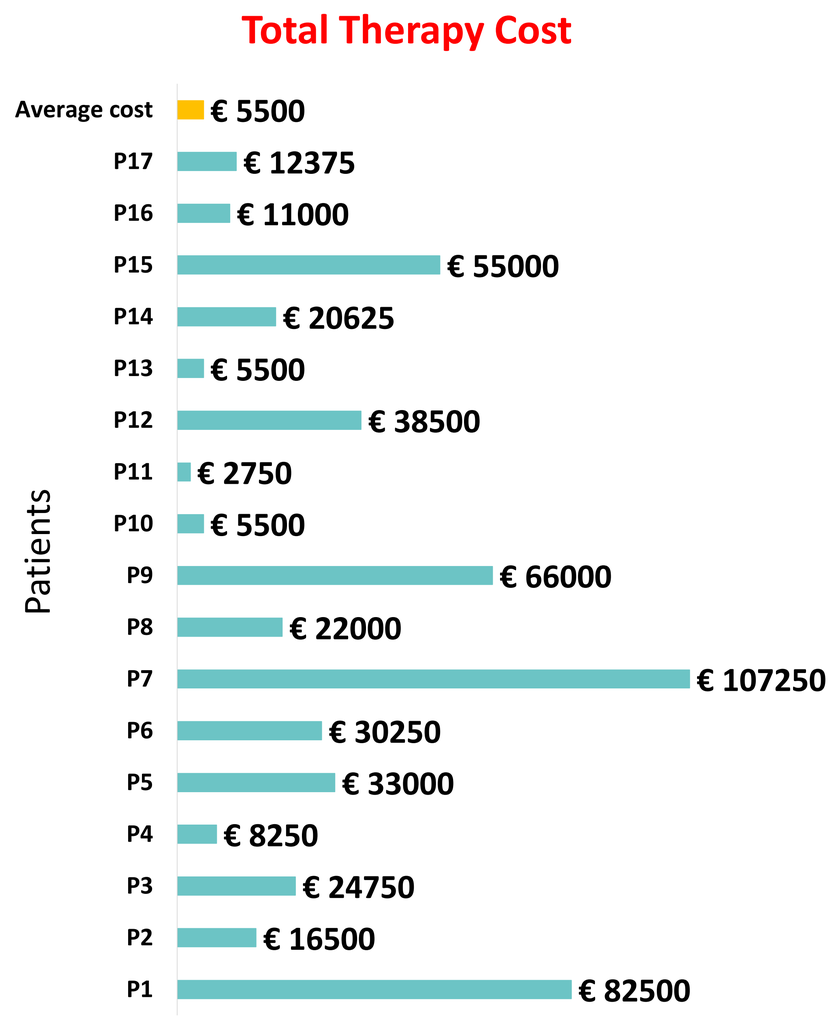

Fig. 2 Total cost of Olaratumab (**blue**) and Average cost of administration (**yellow**) per patient.

The primary outcome of the authorization study showed a better progression-free survival (PFS) (6.6 months), compared to 4.1 months of patients treated with doxorubicin alone.

Only 5 of our patients exceeded this period, but had to discontinued treatment because of disease progression (**Fig. 3**). The total cost of their therapy was € 349250 (48 total cycles for 5 patients). For the other 12 patients the cost was € 192500 (31 total cycles). The average cost of administration (21-day cycles) for the Italian national health service was **€ 5500/patient** (**Fig. 2**).

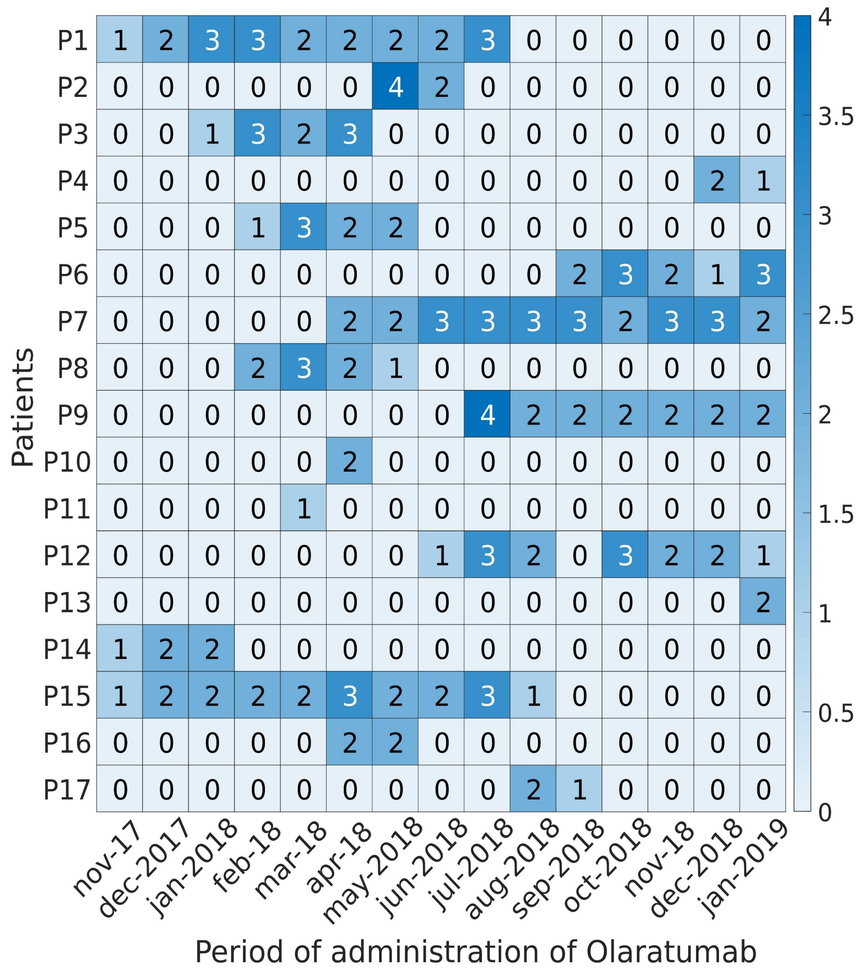

Fig. 3 Number of monthly administration per patient of Olaratumab.

Conclusion

After a conditional marketing authorization, further research costs of the approved drug are necessarily at the expense of Italian national health service. This was the case of Olaratumab, that resulted not effective. For this reason, for fast-track authorization, the reimbursement price of the drugs should take into account post-authorization costs.

Furthermore, it is important to provide a hospital monitoring of the drug clinical effects and consequent cost.

References

(1) Penniman L, Parmar S, Patel K. Olaratumab (Lartruvo): An Innovative Treatment for Soft Tissue Sarcoma. P T. 2018;43(5):267–270.

(2) ClinicalTrials.gov Identifier: NCT01185964

(3) 3 Gennaio 2019 EMA/27962/2019