BIOSIMILAR RITUXIMAB - A YEAR BEYOND

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BACKGROUND

The introduction of a biosimilar drug represents similar efficacy at lower cost, providing savings without compromise patient treatment. In oncology, biological therapies account for more than 33% of health expense[1].

Rituximab has a particular profile of first infusion related reactions (IRR), such as hypersensitivity reactions, hypotension and cardio-respiratory compromise, which may lead to treatment discontinuation[2].

PURPOSE

Evaluate safety profile of biosimilar rituximab in the approved indications and economic impact of the introduction of biosimilar rituximab.

METHODS

Retrospective analysis of first IRR reported to pharmacy services or described in the patient file with biosimilar rituximab, between July 2017 and July 2018. Switch to biosimilar rituximab was performed to all patients.

http://www.eahp.eu/24-4CPS-254

POSTER 4CPS-254

RESULTS

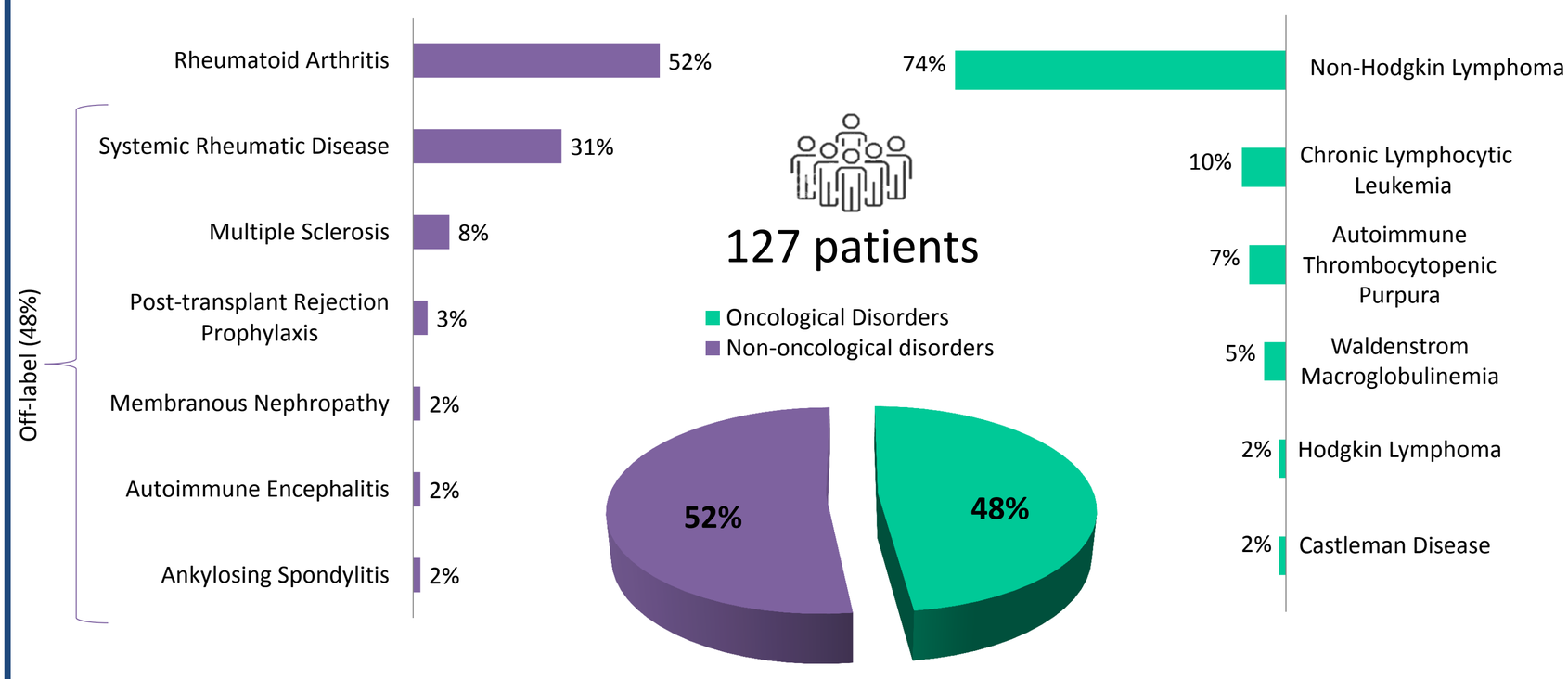

Fig.1- Population Distribution

Oncological Disorders

Therapeutic Switch 9,8%

Naïve Patients 90,2%

Switch Time 34 days [21-58 days]

Mean time between the last administration of rituximab and the first administration of biosimilar rituximab

3 severe first IRR (4,9%) that led to biosimilar rituximab **suspension**

2 successful re-challenge

1 permanent discontinuation

The rate of first IRR was 6.5% in oncological disorders

Non-Oncological Disorders

Therapeutic Switch 39,4%

Naïve Patients 60,6%

Switch Time 13,6 months [0,9-48 months]

No severe first IRR

1 successful re-challenge

The rate of first IRR was 2,9% for Rheumatoid Arthritis (RA)

Biosimilar rituximab introduction resulted into 64% cost reduction, 171.000€

CONCLUSION

Biosimilar rituximab introduction resulted in significant savings (64%) with no major changes in safety profile (4,9% oncological disorders and none for RA of severe first IRR) when compared with the summary of product characteristics of the originator (12% and 0,5%)[2]. The difference may be associated with an underestimated report, since it is a commonly used drug with known IRR profile.

REFERENCES

1] http://www.infarmed.pt/documents/15786/2682984/junho/34525a26-4c19-4035-8132-cfdb29105022?version=1.0
[2] Mabthera SPC available in: https://www.ema.europa.eu/documents/product-information/mabthera-epar-product-information_en.pdf