Pertuzumab Risk Sharing Agreement in the Portuguese NHS: a 4-year experience

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Background and Objective

Risk-sharing agreements (RSA) between payers and pharmaceutical companies have increasingly been used by policy makers as a means to ease pressure on health care budgets medicines expenditure.[1]

Within the scope of Perjeta (pertuzumab) reimbursement evaluation in metastatic breast cancer (mBC) patients, an RSA was established between Infarmed, IP, the Portuguese Health Authority and Roche Portugal in August 2015 and implemented, thereafter, within the Portuguese National Health Service's (NHS) hospitals.[2]

This agreement implies full financial support (free of charge) of the dual HER2+ blockage Perjeta and Herceptin (trastuzumab) - P+H - after a defined treatment period and requires periodical real world data (RWD) collection and reporting by NHS hospitals.

Our aim is to analyse RWD reported in the scope of Perjeta RSA implementation and put it into perspective with already available evidence.

Methods

A quantitative analysis of Perjeta in mBC RSA reporting by NHS hospitals based on anonymous and aggregated patient-level data, collected from its implementation up to April 2019 was performed. Reported data included treatment initiation, administration and discontinuation dates (when available) as well as dosages.

The number of patients encompassed by the agreement, their treatment duration, the number of administered Perjeta and Herceptin cycles, and the time to reporting were analysed.

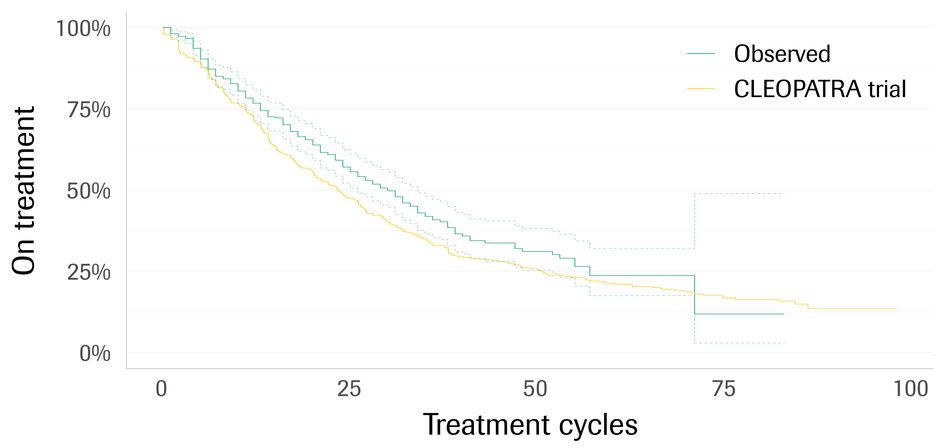
Results

Since its implementation until April 2019, a total of 522 mBC patients were enrolled in the Perjeta in mBC RSA and provided reports of their treatment within 33 NHS hospitals.

Treatment duration and financial impact
From the analysis of the RWD reports, 30% of the mBC patients (158 out of 522) had already reached the 25th treatment cycle and had the opportunity to benefit from at least one P+H treatment cycle fully supported by Roche ("free"). More than half of the patients were still undergoing treatment.

According to Kaplan-Meier survival analysis, median treatment duration with Perjeta was 30 cycles (95% CI 26-34), slightly longer than the one previously obtained in the pivotal phase III CLEOPATRA trial (24 cycles)[3] - *Figure 1*. Consequently, it is estimated that more than half (56%) of the patients will reach the 25th treatment cycle (95% CI: 51-61) and benefit from "free" P+H treatment cycles.

Figure 1: Kaplan-Meier plot for duration of treatment



References

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2. Relatório de avaliação prévia do medicamento para uso humano em meio hospitalar. Available online at https://www.infarmed.pt/15786/1424140/Parecer+net_Perjeta.pdf

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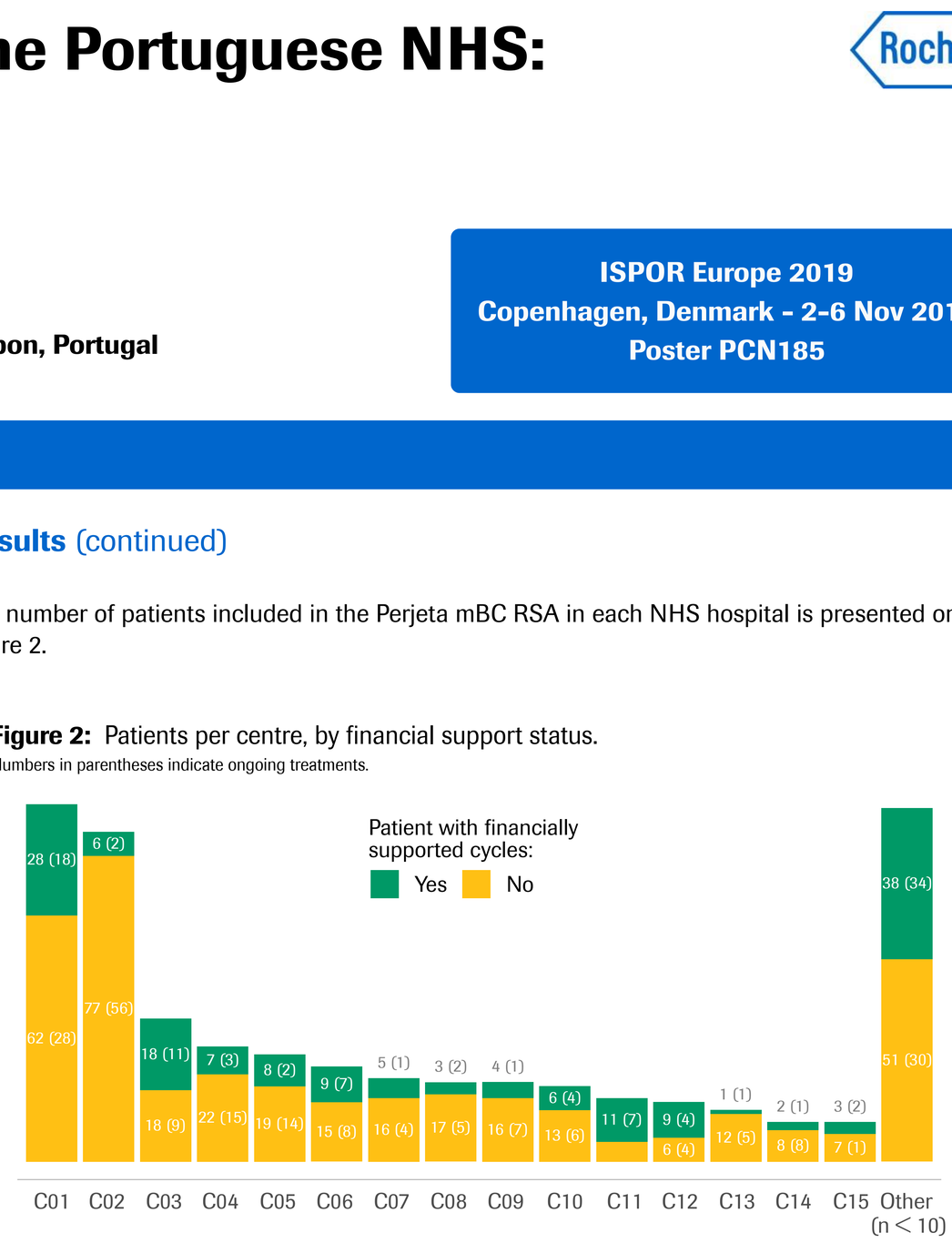
Results (continued)

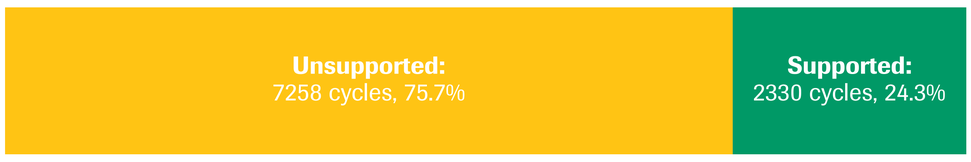
The number of patients included in the Perjeta mBC RSA in each NHS hospital is presented on figure 2.

Figure 2: Patients per centre, by financial support status.
Numbers in parentheses indicate ongoing treatments.



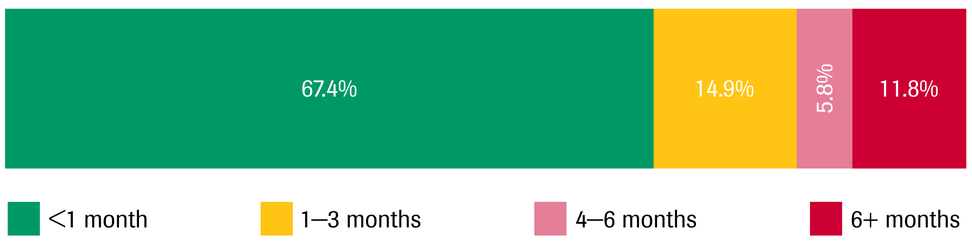
Based on the reported RWD on treatment initiation, administration and discontinuation (when applicable) dates, a total of 9588 treatment cycles with Perjeta and Herceptin were administered, 2330 of which (24.3%) were free for NHS hospitals (fully supported by Roche) in the scope of Perjeta mBC RSA - *Figure 3*.

Figure 3: Treatment cycles by financial support status



Reporting performance
About 71% of the free treatment cycles (cycles eligible to be fully supported by Roche under the RSA) had been reported by the NHS hospitals. In most cases, these cycles were reported within one month since the administration date - *Figure 4*. Reporting lag times ranged from less than a month to 14 months, although the median reporting lag was inferior to one month.

Figure 4: Reporting lag (in months)



Discussion

RWD obtained throughout RSAs implementation is critical to validate initial assumptions and expected overall value.

Perjeta mBC RSA RWD reported by the Portuguese NHS hospitals shows that mBC patients stay on treatment with Perjeta + Herceptin slightly longer than initially expected based on RCT. This suggests better outcomes for these patients (longer progression-free survival) at a similar treatment cost for the Portuguese NHS.

RWD reporting periodicity differs across NHS hospitals. Adequate resources and close monitoring should be guaranteed within NHS hospitals in order to maximize their own financial benefit with Perjeta mBC RSA implementation.

Perjeta mBC RSA represents a viable and valuable mechanism for the Portuguese NHS to predict and control HER2+ mBC drug expenditure.

Acknowledgements

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