**FIRST VALUE-BASED PRICE AGREEMENT IN FRANCE BASED ON PRM REAL-WORLD DATA**

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**1. BACKGROUND & OBJECTIVES**

- The ageing population in line with life expectancy increase, plus the development of chronic diseases are leading to the rise of health expenditures.
- Setting a price for an innovative therapeutic is becoming increasingly complex. An example among others is oncology with the immunotherapies. Due to their multiple uses in different indications in which the benefits vary across patient groups and the size of the patient groups differs too, it is not an easy exercise to set one and unique price for a medicine.
- The personalized reimbursement model (PRM) proposes a number of models where the price will be distinguished by either indications, or therapeutic combinations or even treatment lengths, aiming to reflect the actual patient benefit.
- Those models’ ambition is to allow a fair pricing and consequently ensure health budget sustainability. Therefore, PRM is one option to move further from volume-based to value-based pricing model.

**2. METHODS**

- PRM is a retrospective, non-interventional study based on secondary use of patient data, conducted in French public and non-public hospitals. Retrospective data are extracted two times a year from the chemotherapy Electronic Pharmacy Record (EPR) systems of participating centers.
- The PRM project collects real life data for:
  - All breast cancer women with at least one HER2+ targeted therapy from Roche administrated from January 2011 to May 2019.
  - All lung cancer patients with at least one Roche therapy given from January 2015 to May 2019.
- Data collection were securely performed by an accredited hosting provider, from hospital EPR systems in which useful data are already available, and no study-related involvement from physicians or study nurses is necessary.
- Extracted data included demographic, clinical patient characteristics (year of birth, height and weight), disease stage assessment, and treatments received (treatment line, treatments, dates of administration and doses).
- The database contains 25,000 breast cancer patient files including 21,385 interpretable since 2011 and 3,2161 lung cancer patients including 2,762 interpretable since 2015.
- Data management has been reviewed and validated by a scientific committee.

**RESULTS**

- The price agreement covers Atezolizumab in its lung cancer indication. As this product was launched in February 2019, data have been collected since this date. The next extraction in January 2020 will provide the information for the full 2019 year. Therefore in these results, Roche used data from patients treated by Bevacizumab in 2018 for a non-small cell lung cancer (NSCLC).
- Territorial representation or representativeness by type of centers is controlled by comparing collected data with those from the medicalized information system program (PMSSI). Adjustment factors are computed in order to optimize representativeness.
- Thus, data are representative of patients’ management in France suffering from lung cancer.

**Table 1 : Comparison of distribution of types of centers between PRM database and PMSSI 2017**

<table>
<thead>
<tr>
<th>Types of centers</th>
<th>Patient distribution from PRM centers</th>
<th>Patient distribution from all centers</th>
<th>Adjustment factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public hospital</td>
<td>49%</td>
<td>46%</td>
<td>0.94</td>
</tr>
<tr>
<td>University hospital</td>
<td>14%</td>
<td>23%</td>
<td>1.58</td>
</tr>
<tr>
<td>Cancer center</td>
<td>11%</td>
<td>9%</td>
<td>0.85</td>
</tr>
<tr>
<td>Private clinic</td>
<td>26%</td>
<td>22%</td>
<td>0.84</td>
</tr>
</tbody>
</table>

- Data can be used to identify patient sub-groups. From these different sub-groups it is possible to establish different pricing models based on, for example:
  - Treatment lines. Patient benefit varies from one treatment line to another. We could therefore imagine that the price would evolve as the treatment lines progress.

**Chart 1 : Distribution of patients treated by Bevacizumab by treatment line for a NSCLC**

<table>
<thead>
<tr>
<th></th>
<th>L1 (IIb-IV)</th>
<th>L2 (IIb-IV)</th>
<th>L3 (IIb-IV)</th>
<th>L4+ (IIIb-IV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>11%</td>
<td>18%</td>
<td>61%</td>
<td></td>
</tr>
</tbody>
</table>

**Chart 2 : Distribution of treatment associated with Bevacizumab in 1st line in 2016 for a NSCLC**

*These results reflect the practices of hospitals included in PRM project. These practices may not be in line with product labels. Roche does not recommend off-label use of its products. Any off-label use must be subject of a pharmacovigilance statement.

**Chart 3 : Distribution of patients by number of bevacizumab treatment cycles received for a NSCLC**

- The last criterion stated is the one selected for Atezolizumab price agreement in February 2019.
- In this model, the benefit for patient is measured by the number of treatment cycles administrated taking into consideration that a small number of cycles means either a risk of toxicity issues or a lack of treatment efficacy. Consequently Roche has committed to reimburse all treatments administrated with a small number of cycles to national health insurance.

**DISCUSSION**

PRM is a concrete example of the use of real life data aiming at implementing innovative financing models Nevertheless those innovative models could be more accurate. Indeed, for example in the second model oral treatments are not documented in hospital EPR consequently treatment associations model is suitable only for intravenous treatments. Cross matching PRM data with national healthcare data could be one option to overcome this limit.

**CONCLUSION**

Roche-France succeeded in signing the first price agreement based on PRM data, by developing a robust and representative real-world database. This price agreement is a first step towards a broader approach : open PRM to either indications or drugs or even therapeutic areas with the objective to have a greater impact on the ecosystem. If successful, Roche would be an active contributor in sustaining in the long term the healthcare system with one objective in mind : more access to more innovative drugs for more patients.

**ACKNOWLEDGEMENT**

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**REFERENCES**

Internal document: PRM 2019 extraction.