Dual bronchodilator with QVA149 in patients with severe and very severe COPD
Are there incremental benefits for the Portuguese patients and for the Portuguese NHS when compared to the current treatment options?

INTRODUCTION

COPD is a chronic disease characterized by a persistent airflow limitation that progresses over time. It is one of the leading causes of death worldwide (1), and it affects approximately 100 million patients in Europe alone. In Portugal it is estimated that there are approximately 12,000 COPD patients (2) (of the general population and 14%) in adults aged 40 years or over (3) but despite the high prevalence, the diagnosis is very late (4).

COPD impacts not only the quality of life (QoL) but also the health care system. There is a significant economic burden associated to COPD and a substantial component of that socioeconomic burden is related to the hospitalization for disease exacerbations (5). In European, exacerbation-related costs are considered the major drivers in COPD which account for 52% to 70% of the total COPD-related costs (6). One of the main goals of managing COPD is therefore to reduce the frequency of exacerbations, hospitalisations and emergency room admissions. It is expected that by reducing exacerbations it will decrease the economic burden of the disease.

Evidence suggests that QVA149 (a combination of indacaterol, a long-acting β2-mimetic agonist – LABA, and glycopyrronium bromide, a long-acting muscarinic antagonist – LAMA) offers superior bronchodilatation compared with salmeterol/fluticasone combination (SFC) in patients with moderate to severe COPD, and no exacerbations in the prior year as demonstrated in the LANTERN studies (7). Results from the LANTERN study, the only study in a COPD population, with or without prior exacerbation history (i.e., not excluding high risk patients) have suggested superiority of QVA149 in SFC, in reducing the rate of exacerbations (6). These results indicate that QVA149 can be used as a new treatment option for moderate-to-severe COPD patients with a history of ≥1 exacerbation in the previous year with incremental benefits as SFC.

OBJECTIVE

Quantify the potential clinical benefits and economic impact associated with the use of QVA149 (indacaterol/glycopyrronium 110/50 µg once in a day) and SFC (fluticasone/salmeterol 50/500 µg BID) in the treatment of Portuguese patients with moderate to severe COPD with or without exacerbations.

METHODOLOGY

A cost-utility framework was developed using the LANTERN study data to derive treatment outcomes for QVA149 and SFC. Primary outcomes of interest were COPD exacerbations (moderate or severe) and direct cost for the Portuguese NHS.

Target population

The analysis estimated the potential clinical benefits and economic impact associated to the use of QVA149 and SFC in Portuguese GOLD B patients receiving active (pharmacological) treatment for COPD with or without exacerbations.

Outcomes of interest

The analysis calculated the clinical benefits (COPD exacerbations) and direct medical costs (drug acquisition, cost of treatment exacerbation, etc.) associated to both treatment options (table 1). COPD exacerbations were classified in 3 categories: total, moderate and severe, and mild.

Clinical inputs

The analysis incorporated clinical data from the LANTERN trials, a 2-week, multicentre, randomised, double-blind, double-dummy, parallel-group study, which aimed to assess the efficacy, safety, tolerability of QVA149 compared to SFC in patients with moderate or severe COPD, or no exacerbations or more in the previous year (6). Efficacy criteria for QVA149 and SFC derived from the LANTERN trials are shown in Table 2. In addition, the analysis considered the incidence of exacerbations based on the history of previous exacerbations. In the absence of published epidemiological data that could be used to identify the proportion of patients with a history of exacerbations or with history of exacerbation in the past year the analysis assigned the assumption rate for the overall patient population.

Study perspective and time horizon

The analysis assumed a 1-year time horizon (365 days) and the perspective of the Portuguese NHS.

RESULTS

Scenario analysis

• Scenario 1 – no previous history of exacerbations: The patients in the QVA149 cohort experience 2.435 mild to severe exacerbations (7.988 for QVA149 vs. 10.435 for SFC) and the total cost is inferior: €463,175.870 vs 693,618.475 (QVA149 vs. COPD-SFC (SFC) at 2014 mortality).

• Scenario 2 – previous history of exacerbations: The patients in the QVA149 cohort experience 11.128 moderate to severe exacerbations (17,034 for QVA149 vs. 28,170 for SFC) and the total cost is inferior: €1,733,631.648 vs 2,757,153.605 (QVA149 vs. COPD-SFC (SFC) at 2014 mortality).

• Scenario 3 – cost of treating an exacerbation equal to the cost of ER visit: The patients in the QVA149 cohort experience 4.468 moderate to severe exacerbations (10,783 for QVA149 vs. 15,600 for SFC) and the total cost is superior: €465,757.825 (QVA149 vs. €208,689.602 (SFC).

CONCLUSION

The analysis suggests that when compared with a day 1 Salmeterol/fluticasone combination in the treatment of moderate-to-severe COPD and risk of exacerbation.

The scenario analysis also showed that the potential gains in health outcomes were more moderate to severe exacerbations. SFC associated to the use of QVA149 in patients with moderate-to-severe COPD is consistent in patients with history of exacerbations and without history of exacerbations and it is in both groups is associated with fewer treatment costs.

The analysis also showed that the potential gains in health outcomes were more moderate to severe exacerbations. SFC associated to the use of QVA149 is in patients with moderate-to-severe COPD is consistent in patients with history of exacerbations and without history of exacerbations and it is in both groups is associated with fewer treatment costs.

REFERENCE

Table 3 – Costs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>QVA149 (€)</th>
<th>SFC (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug acquisition (daily cost)</td>
<td>€61,10</td>
<td>€61,36</td>
</tr>
<tr>
<td>Hospitalisation Cost</td>
<td>€112,27</td>
<td>€115 (12)</td>
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<tr>
<td>Moderate to severe exacerbation</td>
<td>€2,044</td>
<td>€2,144 (14)</td>
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</tbody>
</table>

Disclosure

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