3.01 GLYCOPYRRONIUM BROMIDE, powder for inhalation, 50 microgram, Seebri®, Breezhaler®, Novartis Pharmaceuticals Australia Pty Ltd.

1 Purpose of application

1.1 To provide data from the GLISTEN trial when completed, to confirm the assessment of comparative effectiveness and safety of glycopyrronium in combination with LAB/ICS

2 Background

2.1 At the November 2013 meeting, the PBAC recommended a restricted benefit listing of glycopyrronium for patients with COPD, with the same restriction as tiotropium.

2.2 The minutes stated that 'The PBAC requested that the sponsor provide data from the GLISTEN trial when it was completed, to confirm the assessment of comparative effectiveness and safety of glycopyrronium in combination with LAB/ICS'.

2.3 The sponsor provided the publication: Firth et al, Glycopyrronium once-daily significantly improves lung function and health status when combined with salmeterol/fluticasone in patients with COPD: the GLISTEN study—a randomised controlled trial (2015) Thorax.

3 PBAC Outcome

3.1 The PBAC noted the the publication: Firth et al, Glycopyrronium once-daily significantly improves lung function and health status when combined with salmeterol/fluticasone in patients with COPD: the GLISTEN study—a randomised controlled trial. (2015) Thorax.

3.2 The PBAC noted that publication reaffirmed the view of the Committee in November 2013 that glycopyrronium was non-inferior in regards to efficacy and safety with tiotropium.

3.3 The PBAC thanked the sponsor for providing the data from the GLISTEN trial when it was completed.

4 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

5 Sponsor's Comment

The sponsor had no comment.