PUBLIC SUMMARY DOCUMENT

Product: Glycopyrronium bromide, powder for inhalation, 50 microgram, Seebri®, Breezhaler®
Sponsor: Novartis Pharmaceuticals Australia Pty Ltd
Date of PBAC Consideration: November 2013

1. Purpose of Application

The submission requested a Restricted benefit listing of glycopyrronium bromide (glycopyrronium) on the PBS as a once-daily maintenance bronchodilator treatment for patients with chronic obstructive pulmonary disease (COPD).

2. Background

This drug had not previously been considered by the PBAC.

3. Registration Status

Glycopyrronium bromide was TGA registered on 12 November 2012 and is indicated as a once-daily maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).

4. Listing Requested and PBAC's View

Restricted benefit
A once-daily maintenance bronchodilator for patients with chronic obstructive pulmonary disease.

Listing was requested on a cost-minimisation basis with the nominated comparator, tiotropium.

The PBAC considered that the restriction should be the same as the comparator, tiotropium, which is a Restricted benefit for "chronic obstructive pulmonary disease".

5. Clinical Place for the Proposed Therapy

Long-acting muscarinic receptor antagonists (LAMAs), such as glycopyrronium, are recommended in the treatment algorithm for patients with moderate, severe and very severe COPD, and some patients with mild COPD who may be experiencing high levels of breathlessness. LAMAs can be used either as monotherapy or in combination with a long acting β2 agonist (LABA) as patients begin to experience more breathlessness. Where patients are beginning to experience further exacerbations then a bronchodilator with an inhaled corticosteroid (ICS) is currently recommended.

The submission proposed that the PBS listing of glycopyrronium will provide an alternative LAMA, and could be used:

- as monotherapy; or
- in combination with LABA; or
- in combination with LABA and ICS.

The treatment algorithm is based on the COPD-X guidelines. These guidelines are reflective of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines although not identical.

6. Comparator

The submission nominated tiotropium as the main comparator. The PBAC considered that this was appropriate.

7. Clinical Trials

The submission proposed that glycopyrronium will be used instead of tiotropium in:

- monotherapy;
- add-on to LABA; and
- add-on to LABA and ICS

Clinical evidence was provided for each setting.

For monotherapy, the key trial, $GLOW_5$, is a 12-week, multi-centre, double-blinded randomised control non-inferiority trial, of 657 moderate to severe COPD patients.

Three supplementary trials, $GLOW_2$, SHINE and SPARK were also presented:

- $GLOW_2$: 52-week multi-centre, RCT with open label tiotropium of 1,066 randomised moderate to severe COPD patients;
- SHINE: 26-week multi-centre RCT with open label tiotropium of 2,144 randomised moderate to severe COPD patients;
- SPARK: 64-week multi-centre RCT with open label tiotropium of 2,224 randomised severe to very severe COPD patients.

The PBAC noted that the supplementary trials are open-label and that this may favour glycopyrronium. The PBAC noted that the severity of disease of patients in the trials was similar, according to COPD-X (mild to more severe) and GOLD (moderate to more severe) guidelines. Details of the monotherapy trials are presented in the table below.

Trials and associated reports presented in the submission (monotherapy)

Trial ID	Protocol title/ Publication title	Publication citation
Key randomised controlled trial		
$GLOW_5$	A 12-week treatment, randomized, blinded, double-dummy, parallel group study to assess the efficacy, safety and tolerability of NVA237 (50 µg o.d.) in patients with COPD	2013
Supplementary randomised trials		
$GLOW_2$	A 52-week treatment, randomized, double-blind, placebo-controlled, with open-label tiotropium, parallel-group study to assess the efficacy, safety, and tolerability of glycopyrronium bromide (NVA237) in patients with Chronic Obstructive Pulmonary Disease. Kerwin et al. Efficacy and safety of NVA237 versus placebo and tiotropium in patients with COPD: The $GLOW_2$ study.	2011 *European Respiratory Journal (*2012); 40(5): 1106-1114.
SPARK	A 64-week treatment, multi-center, randomised, double-blind, parallel-group, active controlled study to evaluate the effect of QVA149 (110/50µg q.d.) vs NVA237 (50µg q.d.) and open-label tiotropium (18µg q.d.) on COPD exacerbations in patients with severe to very severe chronic obstructive pulmonary disease (COPD). Wedzicha et al. Analysis of chronic obstructive pulmonary disease exacerbations with the dual bronchodilator QVA149 compared with glycopyrronium and tiotropium (SPARK): a randomised, double-blind, parallel-group study.	2012 *The Lancet. (*2013) Published online http://dx.doi.org/10/1016/S2213-2600(13)70052-3
SHINE	A 26-week treatment, multi-center, randomized, double-blind, parallel-group, placebo and active controlled (open label) study to assess the efficacy, safety and tolerability of QVA149 (110/50µg q.d.) in patients with moderate to severe chronic obstructive pulmonary disease (COPD). Bateman et al. Dual bronchodilation with QVA149 versus single bronchodilator therapy: the SHINE study.	2012 *Eur Respir J* (2013), epub ahead of print.

For add-on to LABA therapy, no direct head to head trials were identified. Consequently, the submission presented a network analysis of five trials. The trials included in the network analysis ($GLOW_6$, $INTRUST_1$, $INTRUST_2$, INHANCE and SHINE) are summarised below:

- $GLOW_6$: 12-week multi-centre, RCT, glycopyrronium and indacaterol versus indacaterol, 449 randomised moderate to severe COPD patients;
- $INTRUST_1$: 12-week multi-centre RCT indacaterol and open label tiotropium versus open label tiotropium, 1,134 randomised moderate to severe COPD patients;
- $INTRUST_2$: 12-week multi-centre RCT, indacaterol and open label tiotropium versus open label tiotropium, 1,142 randomised moderate to severe COPD patients;
- INHANCE: 26-week multi-centre RCT,2 doses of indacaterol versus open label tiotropium versus blinded formoterol of 2,059 randomised moderate to severe COPD patients; and
- SHINE: 26-week multi-centre RCT, combined glycopyrronium+indacaterol versus indacaterol versus glycopyrronium versus open label tiotropium versus placebo of 2,144 randomised moderate to severe COPD patients.

Trials and associated reports presented in the submission (add on to LABA)

Trial ID	Protocol title/ Publication title	Publication citation
Indacaterol		
Glycopyrronium and Indacaterol		
$GLOW_6$	A 12-week multi-centre, randomized, double-blind, parallel group study to assess the efficacy, safety and tolerability of the co-administration of NVA237 + indacaterol once daily versus indacaterol once daily in patients with moderate to severe COPD.	2013
Placebo		
SHINE	A 26-week treatment, multi-center, randomized, double-blind, parallel-group, placebo and active controlled (open label) study to assess the efficacy, safety and tolerability of QVA149 (110/50µg q.d.) in patients with moderate to severe chronic obstructive pulmonary disease (COPD). Dual bronchodilation with QVA149 versus single bronchodilator therapy: the SHINE study.	2012 Bateman et al. Eur Respir J 2013, epub ahead of print
Tiotropium		
INHANCE	A 26-week treatment, multi-center, randomized, double-blind, double-dummy, placebo-controlled, adaptive, seamless, parallel-group study to assess the efficacy, safety and tolerability of two doses of indacaterol (selected from 75, 150, 300 & 600 µg o.d.) in patients with chronic obstructive pulmonary disease using blinded formoterol (12 µg b.i.d) and open label tiotropium (18µg o.d.) as active controls Once-daily bronchodilators for chronic obstructive pulmonary disease: indacaterol versus tiotropium.	2008 Donohue et al. Am J Respir Crit Care Med. 2010: 182; 155-162.
Tiotropium		
Tiotropium & Indacaterol		
$INTRUST_1$	A randomized, double-blind, controlled, parallel group, 12-week treatment study to compare the efficacy and safety of the combination of indacaterol 150 µg once daily with open label tiotropium 18 µg once daily versus open label tiotropium 18 µg once daily in patients with moderate-to severe chronic obstructive pulmonary disease Concurrent use of indacaterol plus tiotropium in patients with COPD provides superior bronchodilation compared with tiotropium alone: a randomised, double-blind comparison.	2010 Mahler DA et al. Thorax 2012. 67: 781-788
$INTRUST_2$	A randomized, double-blind, controlled, parallel group, 12-week treatment study to compare the efficacy and safety of the combination of indacaterol 150 µg once daily with open label tiotropium 18 µg once daily versus open label tiotropium 18 µg once daily in patients with moderate-to severe chronic obstructive pulmonary disease Concurrent use of indacaterol plus tiotropium in patients with COPD provides superior bronchodilation compared with tiotropium alone: a randomised, double-blind comparison.	2010 Mahler DA et al. Thorax 2012. 67: 781-788.

For add on to LABA/ICS therapy, one trial (GLISTEN) was presented for the comparison of glycopyrronium with tiotropium. GLISTEN, is a 12-week, multi-centre, double-blinded randomised control non-inferiority trial, of moderate to severe COPD patients. The trial is ongoing with interim results presented in this submission. Details are in the table below.

Trials and associated reports presented in the submission (add-on to LABA/ICS)

Trial ID	Protocol title/ Publication title	Publication citation
Direct randomised trial(s)		
GLISTEN	A multi-centre, randomized, blinded, active-controlled, parallel-group study to compare the efficacy, tolerability and safety of NVA237 compared to tiotropium added on to fluticasone/salmeterol in subjects with chronic obstructive pulmonary disease.	2013

8. Results of Trials

With regard to comparative effectiveness, a meta-analysis of the trough FEV_1 values at different time points from trials used for monotherapy is presented below.

Trial ID	Glycopyrronium		Tiotropium		Mean Difference (95% CI)[a]
	N	LS mean (SE)	N	LS mean (SE)	
Baseline					
$GLOW_5$	316	1.28	319	1.30	
$GLOW_2$	513	1.35	253	1.39	-
SHINE	448	1.28	460	1.27	-
SPARK[b]	494	0.97	492	0.97	-
12 weeks					
$GLOW_5$	316	1.40 (0.02)	319	1.40 (0.02)	0.004 (-0.025, 0.034)
$GLOW_2$	513	1.47 (0.01)	253	1.46 (0.02)	0.014 (-0.019, 0.046)
SHINE	448	1.36 (0.01)	460	1.37 (0.01)	0.000 (-0.03, 0.02)
SPARK[b]	494	1.08 (0.01)	492	1.09 (0.01)	0.000 (-0.03, 0.02)
Meta-analysis (chi-square = 1.18 (p=0.76; i2 = 0%))					-0.004 (-0.021, 0.013)
26 weeks					
$GLOW_2$	451	1.48 (0.09)	233	1.47 (0.01)	**0.050 (0.014, 0.862)**
SHINE	424	1.36 (0.01)	446	1.37 (0.01)	-0.01 (-0.04, 0.02)
SPARK[b]	463	1.07 (0.01)	481	1.08 (0.01)	-0.01 (-0.03, 0.02)
52 weeks					
$GLOW_2$	416	1.41 (0.02)	210	1.39 (0.02)	0.019 (-0.018, 0.057)
SPARK[b]	437	1.06 (0.01)	439	1.06 (0.01)	0.00 (-0.03, 0.02)
64 weeks					
SPARK[b]	417	0.97 (0.01)	423	0.99 (0.01)	-0.01 (-0.04, 0.01)

CI = confidence interval; FAS = full analysis set; italics = conducted during evaluation; LS = least squares; SE = standard error; a = estimated from mixed effects model; b = Severe subgroup

The primary efficacy measure in the $GLOW_5$ trial was the difference between glycopyrronium and tiotropium in trough FEV_1 at week 12, using the per protocol population. This difference was 0 mL (95% CI: -32 mL to 31 mL).

The submission stated that non-inferiority in terms of FEV_1 was achieved as the lower bound of the two-sided 95% confidence interval for the mean treatment difference was greater than -50 mL. The PBAC considered that this was reasonable.

The PBAC noted that the claim of non-inferiority was based on FEV_1 reduction only, and that other clinically important outcomes such as rates of exacerbations were not measured across all trials. Only the SPARK study included the rate of exacerbations.

The table below summarises the trial results used in the network analysis, measuring FEV_1 at 12 weeks.

	Glyco + Indac			Indac			Pbo			Tio			Tio + Indac		
	N	BL	12 (SE)	N	BL	12 (SE)	N	BL	12 (SE)	N	BL	12 (SE)	N	BL	12 (SE)
$GLOW_6$	214	1.32	1.50 (0.01)	214	1.36	1.44 (0.01)									
INHANCE				389	NR	1.46 (0.02)	376	NR	1.28 (0.02)	393	NR	1.42 (0.02)			
SHINE				452	1.28	1.36 (0.01)	211	1.28	1.24 (0.01)	460	1.28	1.37 (0.01)			
$INTRUST_1$										549	NR	1.30 (0.01)	561	NR	1.38 (0.01)
$INTRUST_2$										564	NR	1.27 (0.01)	565	NR	1.34 (0.01)
Mean difference between treatments at 12 weeks (95% CI)															
$GLOW_6$	0.06 (0.03, 0.10)														
INHANCE				0.05 (0.01, 0.09)											
SHINE				0.15 (0.12, 0.18)											
							0.13 (0.10, 0.17)								
$INTRUST_1$										0.08 (0.05, 0.10)					
$INTRUST_2$										0.07 (0.05, 0.09)					

FEV_1 = Forced expiratory volume in one second; SE = standard error; BL = baseline; 12 = week 12 values; NR = not reported

The baseline and week 12 FEV_1 scores were consistent by treatment arm across the randomised control trials (when reported in the clinical trial reports); however there was a difference in baseline FEV_1 between the $GLOW_6$ and SHINE trial.

The PBAC noted that the clinical trial reports for INHANCE, $INTRUST_1$ and $INTRUST_2$ did not report baseline FEV_1. Thus the improvement in each treatment arm could not be reliably determined.

The results of the network analysis are presented in the table below with measurements of trough FEV_1 at 12 weeks.

Comparison / parameter	Estimated effect			
	Mean	SE	95% HDC	
			Lower	Upper
Comparisons vs. placebo [a]				
Glycopyrronium + Indacaterol	0.214	0.002	0.211	0.217
Tiotropium	0.150	0.001	0.148	0.152
Indacaterol	0.130	0.001	0.128	0.132
Tiotropium + Indacaterol	0.176	0.031	0.109	0.245
Indirect comparisons				
Glycopyrronium + Indacaterol vs. Tiotropium + Indacaterol	0.038	0.031	-0.031	0.106
Severity	0.030	0.002	0.026	0.034
Common SD (Median)	0.017	0.000	0.016	0.017

Comparison / parameter	Estimated effect			
	Mean	SE	95% HDC	
			Lower	Upper
Between-trials SD (Median)	0.025	0.013	0.004	0.093

FEV_1 = Forced expiratory volume in one second; HDC = highest density credibility; SE = standard error.
[a] The submission incorrectly labels these comparisons as direct comparisons. These comparisons are in fact with the placebo arm from the SHINE trial.

The PBAC noted that the reliability of the network analysis is affected by the following factors:

- There is significant heterogeneity across the five trials that are used to inform five treatment arms;
- the network analysis has an open structure, which reduces the reliability of such an analysis;
- the sample size informing the comparison of glycopyrronium plus indacaterol is significantly less than tiotropium plus indacaterol;
- the use of 'severe' as a dichotomous covariate rather than a continuous covariate is not well justified;
- the network analysis is sensitive to the choice of posterior probability for the between-trials standard deviation, which is not well justified; and
- results for non-inferiority between glycopyrronium plus indacaterol vs. tiotropium plus indacaterol for severe patient population were not explored.

The results for add on LABA/ICS therapy from the GLISTEN trial interim analysis, the mean change in trough FEV_1 (litres) from baseline to week 12 were presented to the PBAC. As the results of the trial are still ongoing, the PBAC asked that the results be provided when the trial is completed.

The PBAC accepted that glycopyrronium is non-inferior to tiotropium in terms of efficacy and safety, but noted that the studies that best supported the non-inferiority claim were the trials presented for monotherapy.

With regard to comparative harms, the PBAC noted the key adverse events in the trials as presented in the table below.

Trial ID	Glycopyrronium n(%)	Tiotropium n(%)	RR (95% CI)
$GLOW_5$, N	327	330	
Patients ≥1 AE	132 (40.4%)	134 (40.6%)	*0.99 (0.83,1.20)*
Urinary tract infection	4 (1.2%)	1 (0.3%)	*4.04 (0.45, 35.9)*
Serious or significant AE	11 (3.4%)	13 (3.9%)	*0.85 (0.39, 1.88)*
Discontinuation to AE	7 (2.1%)	5 (1.5%)	*1.41 (0.45, 4.41)*
Death	0	0	-
$GLOW_2$, N	525	267	
Patients ≥1 AE	402 (76.6%)	198 (74.2%)	*1.03 (0.95, 1.12)*
Urinary tract infection	14 (2.7%)	16 (6.0%)	***0.45 (0.22, 0.90)***
Cardiac /cerebrovascular	64 (12.2%)	22 (8.2%)	*1.48 (0.93, 2.35)*
Serious or significant AE	65 (12.4%)	43 (16.0%)	*0.77 (0.54, 1.10)*
Discontinuation to AE	42 (8.0%)	31 (11.6%)	*0.69 (0.44, 1.07)*
Death	2	2	*0.51 (0.07, 3.59)*
SHINE, N	473	480	
Patients ≥1 AE	290 (61.3%)	275 (57.3%)	*1.07 (0.96, 1.19)*
Atrial fibrillation	3 (0.6%)	0 (0%)	*7.10 (0.37, 137.2)*[a]
Serious or significant AE	29 (6.1%)	19 (4.0%)	*1.55 (0.88, 2.72)*

Discontinuation to AE	14 (3.0%)	10 (2.1%)	*1.42 (0.64, 3.17)*
Death	2 (0.4%)	3 (0.6%)	*0.68 (0.11, 4.03)*
SPARK, N	584	480	
Patients ≥1 AE	543 (93.0%)	*451* (94.1%)	*0.99 (0.96, 1.02)*
Serious / discontinue AE	194 (33.2%)	145 (30.2%)	*1.10 (0.92, 1.31)*
Death	14 (2.4%)	15 (2.6%)	*0.77 (0.37, 1.57)*

AE = adverse events; CI = confidence interval; RR = relative risk
[a] Calculated by increasing each trial arm by 0.5 a case;

The PBAC noted that there were limited safety data for combination therapy with LABA/ICS, as the interim results in the GLISTEN trial were based on a small sample population. Nonetheless, the PBAC acknowledged that there were no safety signals from the use of glycopyrronium, and across the trials presented, there were no statistically significant differences in the occurrence of adverse events or serious adverse events between glycopyrronium and tiotropium. On balance the PBAC considered that there were no grounds for concern regarding the relative safety of glycopyrronium and tiotropium.

The PBAC recalled that tiotropium was recommended on the basis of acceptable cost-effectiveness compared with ipratropium bromide. The PBAC recalled that patients treated with tiotropium experienced fewer exacerbations compared to ipratropium.

9. Clinical Claim

For monotherapy, the submission described glycopyrronium as non-inferior in terms of comparative effectiveness and equivalent in terms of comparative safety over tiotropium.

The PBAC agreed that it was reasonable to accept that glycopyrronium monotherapy is non-inferior to tiotropium in terms of comparative effectiveness and equivalent in terms of comparative safety.

For combination LABA therapy, based on the network analysis, the submission described glycopyrronium plus indacaterol as non-inferior in terms of comparative effectiveness. In terms of the safety profile, the submission claimed no statistically significant differences compared with tiotropium plus indacaterol.

The PBAC noted the issues listed above with the claim of non-inferior comparative efficacy based on the network analysis, and considered that the network analysis was not informative for decision-making.

For combination LABA/ICS therapy, the submission described glycopyrronium and fluticasone/salmeterol combination (FSC) as non-inferior in terms of comparative effectiveness and equivalent in terms of comparative safety over tiotropium and FSC. The PBAC considered the claim to be adequately supported on the basis of the results from the GLISTEN trial, however noted that the available data are limited data as the trial is ongoing.

10. Economic Analysis

The submission presented a cost-minimisation analysis based on the non-inferiority claim supported by the results for trough FEV_1 at 12 weeks, without any additional costs or offsets.

The PBAC agreed that a cost-minimisation analysis was the correct approach based on the evidence presented.

The PBAC considered that the monotherapy trials were the best evidence for the economic claim.

The equi-effective doses were estimated as glycopyrronium 50 microgram once daily and tiotropium 18 microgram once daily. The PBAC considered this to be appropriate.

11. Estimated PBS Usage and Financial Implications

The submission presented a market share approach for estimating utilisation and net financial implications of listing glycopyrronium on the PBS. The estimated number of glycopyrronium packs dispensed over the first 5 years of listing was greater than 2 million. The submission claimed that there is no net cost to PBS due to cost offsets in tiotropium substitution.

The PBAC noted the sponsor's comment in its Pre-Sub-Committee Response that "The COPD market is a mature market and as such it is unlikely that the addition of a drug which is not a new category of drug and which is not significantly differentiated from the drug currently on the market is likely to lead to growth". However, the PBAC agreed with the Drug Utilisation Sub-Committee (DUSC) that the introduction of a second pharmaceutical in a therapeutic class may increase the overall market size, rather than substituting solely within the existing market.

The PBAC noted that the following factors may mean the financial implications were underestimated:

- Replacement of LABA/ICS combinations by glycopyrronium as well as replacement of tiotropium.
- The market may grow as a result of listing a second treatment option
- The estimates for the market growth reducing from 8% to 5% over 5 years were not adequately justified.
- Risk of leakage to patients with mild COPD.

Overall, the PBAC considered that the submission's assumptions regarding the total market size were not justified, as it is unclear whether the market will grow with the addition of glycopyrronium. The PBAC considered that if the PBS listing of glycopyrronium results in market growth, a net cost to the Commonwealth would result. However, the PBAC accepted the assumptions made in market share estimates and recommended that the Department enter into a Risk Share Agreement to manage the risks of larger than predicted market growth and leakage into the mild COPD market.

12. Recommendation and Reasons

The PBAC recommended a restricted benefit listing of glycopyrronium for patients with COPD, with the same restriction as tiotropium, therefore excluding the 'once daily' dosing from the requested restriction.

The PBAC made its recommendation based on a cost-minimisation comparison with tiotropium. The equi-effective doses accepted for the purposes of cost-minimisation are glycopyrronium 50 microgram once daily being equivalent to tiotropium 18 microgram once daily.

The PBAC accepted that glycopyrronium was non-inferior in regards to efficacy and safety with tiotropium, but noted that the studies that best supported the non-inferiority claim were the trials presented for monotherapy.

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 LABA/ICS.

The PBAC considered that there are factors that may affect the utilisation of glycopyrronium, including the following:
- listing of glycopyrronium may increase the LAMA market, thus leading to additional costs;
- there is a risk of leakage to patients with mild COPD; and
- overall market growth.

Therefore, the PBAC recommended a risk share agreement be put in place to mitigate larger than predicted market growth and the risk of leakage into the mild COPD market and also advised that the DUSC monitor the market for COPD.

The PBAC noted the similarity of the trade names for glycopyrronium (Seebri®) and tiotropium (Spiriva®), and considered that this may create confusion among both prescribers and patients with the risk of inadvertent co-administration of two LAMA products. Also, given the significant number of PBS-listed inhalers for respiratory diseases, the PBAC noted the risk of patient confusion, particularly regarding the availability of multiple inhaler devices. The PBAC referred this issue to the National Prescribing Service (NPS).

The PBAC advised that glycopyrronium is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.

The PBAC advised the Minister that under Section 101 3BA of the National Health Act, glycopyrronium should be treated as interchangeable on an individual patient basis with tiotropium.

Outcome:
Recommended

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
GLYCOPYRRONIUM BROMIDE glycopyrronium bromide, 50 microgram inhalation: powder for, 30 capsules	1	5	Seebri® BREEZHALER® Novartis

Condition:	Chronic obstructive pulmonary disease
Restriction:	Restricted Benefit

13. 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.

14. Sponsor's Comment

The sponsor had no comment.