

Prof Eric Bateman has served on advisory boards for Boehringer Ingelheim, AstraZeneca, Elevation Pharma, Napp Pharma, Novartis, Almirall, Forest, and Merck and Takeda; has served as a consultant to Navigant Consulting, IMS consulting group, ALK-Abello, Almirall, Hoffman la Roche, and ICON; has been paid lecture fees by AstraZeneca, ALK-Abello, Chiesi, Boehringer Ingelheim, GlaxoSmithKline, Nycomed/Takeda, Novartis, Pfizer, and Indegene Lifesciences Ltd.

Prof Shu Hashimoto has no conflicts of interest.

**P194 ONCE-DAILY QVA149 PROVIDES SUPERIOR BRONCHODILATION AND IMPROVES LUNG FUNCTION VERSUS TWICE-DAILY FLUTICASONE/SALMETEROL IN COPD PATIENTS: THE ILLUMINATE STUDY**

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<sup>1</sup>C Vogelmeier, <sup>2</sup>E Bateman, <sup>3</sup>J Pallante, H Bryant<sup>4</sup>, <sup>5</sup>V Alagappan, <sup>6</sup>P D'Andrea, <sup>7</sup>E He, <sup>8</sup>D Banerji. <sup>1</sup>Department for Respiratory Diseases, University of Marburg, Marburg, Germany; <sup>2</sup>Department of Medicine, University of Cape Town, Cape Town, South Africa; <sup>3</sup>Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; <sup>4</sup>Novartis Horsham Research Centre, Horsham, West Sussex, UK

**Introduction** QVA149 is a novel inhaled once-daily dual bronchodilator containing a fixed-dose combination of the long-acting  $\beta_2$ -agonist (LABA) indacaterol and the long-acting muscarinic antagonist (LAMA) glycopyrronium, in development for the maintenance treatment of COPD. This study evaluated the superiority of QVA149 once daily in terms of efficacy over fluticasone/salmeterol twice daily in patients with COPD.

**Methods** In this 26 week, multicentre, double-blind, double-dummy, parallel-group study patients aged  $\geq 40$  years with moderate-to-severe COPD (post-bronchodilator  $FEV_1/FVC < 0.7$  and  $FEV_1 \geq 40\%$  to  $< 80\%$  predicted), no history of exacerbations in the previous year and smoking history  $\geq 10$  pack-years, were randomised (1:1) to receive QVA149 110/50 $\mu$ g (via the Breezhaler<sup>®</sup> device) or fluticasone/salmeterol 500/50 $\mu$ g (via the Accuhaler<sup>®</sup> device). The primary efficacy end point was standardised  $FEV_1$  area under the curve ( $FEV_1 AUC_{0-12h}$ ) at Week 26. The pre-dose trough  $FEV_1$  on Week 12 and 26 and peak  $FEV_1$  on Day 1, Week 12 and Week 26 were also measured.

**Results** A total of 523 patients (35.1% on inhaled corticosteroids use) were randomised [QVA149, n=259; fluticasone/salmeterol, n=264; male (70.9%); mean age: 63.3 years; mean post-bronchodilator  $FEV_1$ : 60.2% predicted], 82.6% completed.  $FEV_1 AUC_{0-12h}$  was found clinically meaningful and statistically significant in favour of QVA149 compared to fluticasone/salmeterol on Day 1, Week 12 and Week 26 (Least squares mean [LSM] treatment difference=70mL, 120mL, 140mL, respectively; all  $p < 0.001$ ). Pre-dose trough  $FEV_1$  was significantly ( $p < 0.001$ ) higher for QVA149 compared with fluticasone/salmeterol at Week 12 and 26 (LSM treatment difference=90mL and 100mL, respectively;  $p < 0.001$ ). The LSM treatment difference for peak  $FEV_1$  was also statistically significant for QVA149 compared with fluticasone/salmeterol on Day 1 (70mL), Week 12 (150mL) and Week 26 (150mL), all  $p < 0.001$ .

**Conclusion** QVA149 once daily provided superior bronchodilation at all time-points compared to fluticasone/salmeterol twice daily and showed clinically meaningful improvements in lung function for a sustained period of 26 weeks. In moderate-to-severe COPD patients without a history of exacerbations in the previous year, LABA/LAMA dual bronchodilation with once-daily QVA149 proves a superior alternative to twice-daily fluticasone/salmeterol.

Prof Claus Vogelmeier has served on scientific advisory boards for AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Janssen, Novartis, Pfizer, Almirall, Takeda, and Sterna Biologicals; has been paid lecture fees by AstraZeneca, Chiesi, GlaxoSmithKline, Janssen, Talecris, Novartis, Boehringer Ingelheim, Takeda, and Pfizer.

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**Lung cancer investigation, treatment and survival**

**P195 CASE SERIES: HOW USEFUL ARE FLEISCHNER GUIDELINES FOR NODULE SURVEILLANCE IN A DISTRICT GENERAL HOSPITAL?**

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RW Lee, KE Millward, FE Ossai, D Ellis, M Townsend, S Lohani Darent Valley Hospital, Dartford, Kent, United Kingdom

**Background** Surveillance of pulmonary nodules aims to identify early-stage lung cancers where radical therapy can offer cure. Interval CT scans track nodule characteristics with Fleischner criteria commonly used in an attempt to standardise care. There remains debate regarding the applicability of Fleischner guidance in populations of UK patients that can differ substantially from those included in existing studies that define the Fleischner recommendations.

**Objectives**

- Audit compliance of pulmonary nodule follow up with Fleischner Guidelines.
- Compare local outcomes with those used to create Fleischner guidelines.
- Compare local compliance with published compliance.

**Methods** Patients referred to a specialist respiratory nurse service for pulmonary nodule surveillance since 2008 (including patients already under surveillance) with opportunity for 2 years of completed follow-up were included with retrospective review of the nodule database/electronic records and imaging. Patients were risk stratified according to nodule size and Fleischner risk category (e.g. smoking).

**Results** 111 patients under surveillance were identified of whom 56 were Male and 55 Female with median age 67 (34–91) years. 67 were solitary and 44 were multiple. Patients were stratified to Low- and High-risk groups according to main nodule size: (L1–4 or H1–4 respectively). Each group included; High-risk: H1 ( $\leq 4$ mm) 10, H2 ( $> 4-6$ mm) 25, H3 ( $> 6-8$ mm) 19 and H4 ( $> 8$ mm) 36 cases and Low-risk: L1 ( $\leq 4$ mm) 0, L2 ( $> 4-6$ mm) 5, L3 ( $> 6-8$ mm) 4 and L4 ( $> 8$ mm) 3 cases.

89 patients completed standard follow-up and were discharged. Positive scans included Lung tumours (3) - (two underwent lobectomy); Aspergilloma (1); Rectal carcinoma (1)- discovered by non-Fleischner abdominal CT. Surveillance was discontinued for: Patient choice/co-morbidity (8); Nodule resolution (3); Not documented/lost (6).

**Conclusion** Fleischner guidelines were well adhered to and were also utilised where their application is less well defined e.g. development of a new nodule during follow-up prompted either re-initiation or more commonly continued/modified trajectory of Fleischner - an area notably not well covered in current guidance. Furthermore principals of Fleischner recommendations were applied to multiple nodules but management of such patients is often not as easily followed as solitary nodules.

MacMahon et al, University of Chicago, Radiology 2005; 237:295–400.