

than 10,000 downloads (2) a score of 3.5 or higher on the Mobile Apps Rating System (MARS) and (3) acquisition cost less than \$1. Consumer reviews were scanned. A total of 7 apps were culled from an expanding universe of thousands. This included top-rated apps in each of three symptom domains: depression, anxiety and cognitive disorders. Ranked in order of MARS rating the leading depression apps were “Depression CBT Self-Help Guide” and “eCBT Mood”. The most popular anxiety apps were “Stop Panic & Anxiety” and “Headspace”. The top apps for cognitive enhancement training were “Brain HQ” and “Fit Brains Focus”. In addition, the suicide prevention app “My3” was included because of its life saving potential. Consumers have rated the reviewed apps favorably. Conclusion: Smartphone apps are achieving wide acceptance in self-management of common psychiatric disorders. Clinicians need to become familiar with these adjunctive therapeutic tools, and integrate them in brief psychopharmacology visits.

**FUNDING ACKNOWLEDGEMENTS:** No funding.

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### Use of Pimavanserin in Patients With Parkinson’s Disease Psychosis: Subgroup Analysis of Efficacy and Safety in Patients With and Without Cognitive Impairment

*Daniel Weintraub, MD<sup>1</sup>; James Norton, PhD<sup>2</sup>; Bruce Coate, MPH<sup>3</sup>; Candace Andersson, PhD<sup>4</sup>; Doral Fredericks, MBA, PharmD<sup>5</sup>; and Clive Ballard, MD<sup>6</sup>*

<sup>1</sup> Professor of Psychiatry and Neurology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

<sup>2</sup> Sr. Dir. Medical Affairs, ACADIA Pharmaceuticals Inc., San Diego, CA

<sup>3</sup> Associate Director Biostatistics, ACADIA Pharmaceuticals Inc., San Diego, CA

<sup>4</sup> Sr. Medical Science Liaison, ACADIA Pharmaceuticals Inc., San Diego, CA

<sup>5</sup> Vice President Medical Affairs, ACADIA Pharmaceuticals Inc., San Diego, CA

<sup>6</sup> Pro-Vice-Chancellor and Executive Dean, The University of Exeter Medical School, Exeter, UK

**ABSTRACT:** Objective: A planned subgroup analysis of a phase 3 study was performed to evaluate the efficacy and safety of pimavanserin (PIM) in Parkinson’s disease psychosis (PDP) patients with global cognitive impairment.

**BACKGROUND:** PDP is frequent, distressing, a leading cause of institutionalization, complicates PD management and is linked to increased morbidity, incident dementia and mortality. PIM, a selective serotonin

receptor (5-HT<sub>2A</sub>) inverse agonist/antagonist, is newly FDA-approved for the treatment of hallucinations and delusions associated with PDP.

**METHODS:** In Study 020, a 6-week FDA registration study, 199 patients with baseline Mini-Mental State Examination (MMSE) score  $\geq 21$ , moderate-severe psychosis, and on stable PD meds, were randomized to PIM (34 mg/day) or placebo (PBO) for 6 weeks. This subgroup analysis evaluates efficacy and safety between two groups: those with MMSE total score  $\geq 21$  but  $< 25$  (cognitively impaired; equivalent to Montreal Cognitive Assessment [MoCA] score 15-19) and those with score  $\geq 25$  (cognitively normal; equivalent to MoCA score 20-30). Safety assessments were performed on the full safety dataset (i.e., three 6-week placebo-controlled studies) including 614 subjects (PIM = 382, PBO = 231).

**RESULTS:** Overall, patients in the PIM group experienced a statistically significant improvement in SAPS-PD scores from baseline to Day 43 compared with PBO (-5.79 vs. -2.73;  $p = 0.001$ ). In the subgroup analysis stratifying by baseline MMSE score, the change from baseline to Day 43 compared with PBO in the cognitively-impaired group (N = 50) was numerically larger (-7.11 vs. -0.47;  $p = 0.002$ ). In the full safety dataset examining cognitively impaired patients, there were no between-group (PIM vs. PBO) differences in any treatment-emergent adverse event (TEAE) (57.6% vs. 56.1%) or serious TEAE (6.8% vs. 5.3%). The most common TEAEs occurring at  $\geq 5\%$  in either group were fall (7.4% vs. 10.5%), confusional state (6.5% vs. 1.8%), and orthostatic hypotension (0.0% vs. 8.8%).

**CONCLUSIONS:** In this subgroup analysis of PDP patients, the treatment effect of PIM on SAPS-PD was larger in the cognitively-impaired group, with similar TEAE and serious TEAE rates. These results hold promise for cognitively-impaired patients that will be further elucidated in future studies.

**FUNDING ACKNOWLEDGEMENTS:** Clinical study was funded by ACADIA Pharmaceuticals Inc.

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### Adjunctive Brexpiprazole in Patients With MDD and Symptoms of Anxiety: Results From Post-Hoc Analyses of Three Placebo-Controlled Studies

*Emmanuelle Weiller, PsyD<sup>1</sup>; Anna-Greta Nylander, PhD<sup>2</sup>; Catherine Weiss, PhD<sup>3</sup>; Peter Zhang, PhD<sup>4</sup>; and Mary Hobart, MD<sup>5</sup>*

<sup>1</sup> Lead Medical Advisor, Medical Affairs, H. Lundbeck A/S, Valby, Denmark

<sup>2</sup> Director, Head of Corporate Medical Affairs, H. Lundbeck A/S, Valby, Denmark

<sup>3</sup> Director, Global Medical Affairs, Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, USA

<sup>4</sup> Senior Director, Biostatistics, Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, USA

<sup>5</sup> Senior Director, Global Medical Affairs, Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, USA

**ABSTRACT:** Study objectives: Symptoms of anxiety are prevalent in Major Depressive Disorder (MDD) and are associated with greater illness severity, suicidality, impaired functioning and poor response to antidepressant treatment (ADT). In MDD, anxiety symptoms can be assessed as 'anxious distress' (new DSM-5 specifier) or 'anxious depression' (score  $\geq 7$  on the HAM-D anxiety/somatization factor). Brexpiprazole is a serotonin-dopamine activity modulator that is a partial agonist at 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors, and an antagonist at 5-HT<sub>2A</sub> and noradrenaline  $\alpha 1B/2C$  receptors – all at similar potency. Brexpiprazole is approved in the US for treatment of schizophrenia, and as adjunctive treatment in MDD. The objective of this post-hoc analysis was to assess the efficacy of brexpiprazole as adjunct to ADT in patients with MDD and anxiety symptoms, using these two definitions of anxiety.

**METHODS:** Data were pooled from three randomized, double-blind, placebo-controlled studies with similar designs (Pyxis – NCT01360645; Polaris – NCT01360632; Sirius – NCT02196506). In each study, patients with MDD and an inadequate response to 1–3 ADTs received single-blind ADT for 8 weeks. Patients with inadequate response throughout this prospective phase were randomized to receive either ADT+brexpiprazole (2mg in Pyxis and Sirius; 1mg or 3 mg in Polaris) or ADT+placebo for 6 weeks. Proxies used to categorize patients as having 'anxious distress' included a score of  $\geq 2$  on the following symptoms at randomization: tension (MADRS item 3 score  $\geq 3$ ); restlessness (IDS item 24 score  $\geq 2$ ); concentration (MADRS item 6 score  $\geq 3$ ); or apprehension (HAM-D item 10 score  $\geq 3$ ). Scores on the items of the HAM-D anxiety/somatization factor at randomization (baseline) were used to identify patients with 'anxious depression'. Efficacy was assessed as the change in MADRS total score from baseline to Week 6. Statistical analysis used a Mixed Model Repeated Measure approach using pooled brexpiprazole doses.

**RESULTS:** After 8 weeks of prospective ADT monotherapy, 57.6% (n = 797/1,383) of patients met the criteria for anxious distress, and 48.5% (n = 671/1,383) for anxious depression. The mean MADRS total score was

29.0 for patients with anxious distress in the adjunctive brexpiprazole (n = 462) group and 29.1 in the placebo (n = 327) group; while those with anxious depression were 28.9 (brexpiprazole; n = 384) and 28.6 (placebo; n = 282). Compared to those receiving placebo, patients with both anxious distress and anxious depression who received adjunctive brexpiprazole showed a greater improvement in MADRS total score (LS mean difference -2.38, p = 0.0001 and -1.68, p = 0.012, respectively). These improvements, compared to placebo, were similar to those in patients who had not met the criteria for anxious distress (-1.40, p = 0.023) or anxious depression (-2.17, p < 0.001).

**CONCLUSION:** Adjunctive brexpiprazole may be efficacious in reducing depressive symptoms both in patients with or without symptoms of anxiety.

**FUNDING ACKNOWLEDGEMENTS:** The studies were funded by H. Lundbeck A/S and Otsuka Pharmaceutical Development & Commercialization, Inc.

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### Epochs of Anosmia and Ageusia in Multiple Sclerosis: Chemosensory Uthoff's Phenomenon

*Davinder Dhillon<sup>1</sup>; Jasir T Nayati<sup>2</sup>; Priya Batta<sup>3</sup>; and Alan R. Hirsch, MD<sup>4</sup>*

<sup>1</sup> Windsor School of Medicine, Basseterre, St. Kitts

<sup>2</sup> St. James School Of Medicine, Park Ridge, IL / Anguilla Campus

<sup>3</sup> Windsor School of Medicine, Basseterre, St. Kitts

<sup>4</sup> Smell and Taste Treatment and Research Foundation, Chicago, IL

**ABSTRACT:** Study Objective: To reveal that while long duration of anosmia and ageusia has been seen with Multiple Sclerosis (MS) [Doty 1997], repetitive shorter epochs of anosmia and ageusia has not heretofore been presented.

**METHODS:** Case Study: A 39 year old right-handed male, with a history of MS, presents with six years MS concurrent with epochs of anosmia and ageusia. The anosmia and ageusia present concurrently, preventing him from smelling and tasting his meal. At baseline, he is able to smell and taste coffee, peppermint, gum, sweet and salty foods, rating his smell and taste at 70% normal. However, during the epochal events, he reports the inability to smell and taste white rice, shrimp, meat, butter, carrots, onions, spinach, and sour foods. He states that these episodes occur approximately ten times a week, last for two hours, and rates his smell and taste from 0-10% during these events.