Safety and tolerability of overactive bladder treatments using a large integrated database of mirabegron clinical studies involving >10,000 overactive bladder patients

Chapple CR1, Cruz F2, Heesakkers J3, Cardozo L4, Milsom I5, Wagg A6, Staskin D7, Herschorn S8, Stoelzel M9, Schermer L10, Patient-Centricity Research Support, Leiden, The Netherlands; 11Royal Hallamshire Hospital, Sheffield, UK; 12Hospital S João and Faculty of Medicine/i3S Institute, Porto, Portugal; 13Radboudumc University Medical Centre, Nijmegen, The Netherlands; 14Astellas Pharma US, Medical Affairs, Americas, Northbrook, IL, USA; 15Astellas Pharma, Global Medical Affairs, Chertsey, Surrey, UK

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OBJECTIVE
To assess safety and tolerability of mirabegron and antimuscarinics using a large integrated database (IDB) of data from patients with OAB

METHODS
• Included all adults who received ≥2 doses of monotherapy study drug (placebo, mirabegron 25 mg/50 mg, solifenacin 2.5 mg/5 mg/10 mg, tolterodine ER 4 mg) for overactive bladder (OAB) symptoms in 11 double-blind, 13-week, Phase II–IV global mirabegron studies11
• Data presented for aggregated treatment groups (total mirabegron, total antimuscarinics, placebo)
• Treatment-emergent adverse events (TEAEs) defined as any adverse event observed after starting study drug
• Good Clinical Practice guidelines and Principles of Declaration adhered to; written informed consent obtained

DISCLOSURES
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11,261 PATIENTS
78.5% of patients were female and the majority were white with a mean age of 75.7 years

OAB SYMPTOMS
6–7% more patients receiving antimuscarins had frequency/urgency without incontinence and 6–14% fewer had mixed incontinence vs mirabegron and placebo

PRIOR OAB TREATMENT HISTORY
Discontinuations were 3–4 times more frequent due to lack of efficacy than to poor tolerability in all groups

OVERVIEW OF TEAEs AND TREATMENT DISCONTINUATION STATUS

DRUG-RELATED TEAE FREQUENCY
Frequency of drug-related TEAEs slightly higher for antimuscarinics than for mirabegron

DRIY MOUTH
More frequent for antimuscarinics than for mirabegron

CARDIOVASCULAR AND URINARY RETENTION TEAEs
Low frequency in all groups

LARGE IDB
Reaffirms the safety profiles of mirabegron, solifenacin and tolterodine

REFERENCES