## LOW INCIDENCE OF CLEAN INTERMITTENT CATHETERIZATION WITH ONABOTULINUMTOXINA IN DIVERSE AGE GROUPS OF OVERACTIVE BLADDER PATIENTS WITH SUBSTANTIAL IMPROVEMENTS IN TREATMENT RESPONSE

<u>Stefano Salvatore</u>, <sup>1</sup> Marcus Drake, <sup>2</sup> Karel Everaert, <sup>3</sup> Eric Rovner, <sup>4</sup> Roger Dmochowski, <sup>5</sup> David Ginsberg, <sup>6</sup> Sidney Radomski, <sup>7</sup> Tamer Aboushwareb, <sup>8</sup> Cheng-Tao Chang, <sup>9</sup> Christopher Chapple, <sup>10</sup> Victor Nitti<sup>11</sup>

<sup>1</sup>Department of Urogynaecology, San Raffaele Hospital, Milan, Italy; <sup>2</sup>Department of Urology, Bristol Urological Institute, Bristol, UK; <sup>3</sup>Department of Urology, Ghent University Hospital, Ghent, Belgium; <sup>4</sup>Department of Urology, Medical University of South Carolina, Charleston, SC, USA; <sup>5</sup>Department of Urology, Vanderbilt University Medical Center, Nashville, TN, USA; <sup>6</sup>Department of Urology, USC Institute of Urology, Los Angeles, CA, USA; <sup>7</sup>Department of Urology, University of Toronto, Toronto, ON, Canada; <sup>8</sup>Department of Urology, Allergan plc, Irvine, CA, USA; <sup>9</sup>Department of Statistics, Allergan plc, Bridgewater, NJ, USA; <sup>10</sup>Department of Urology, The Royal Hallamshire Hospital, Sheffield Teaching Hospitals, NHS Foundation Trust, Sheffield, UK; <sup>11</sup>Department of Uro-Gynecology and Urology, New York University Langone Medical Center, New York, NY, USA

**Objective:** To determine clean intermittent catheterization (CIC) risk and onabotulinumtoxinA treatment response in diverse age groups of OAB patients.

Materials/Methods: Pooled data from onabotulinumtoxinA-treated patients in three randomized, controlled trials (N=1177) were analyzed (post-hoc) by age: <40, 40-49, 50-59, 60-69 and ≥70 years. Week 12 assessments post-treatment included CIC incidence and duration, %change from baseline in urinary incontinence (UI) episodes/day, proportions of patients with ≥50%UI reduction, positive response (urinary symptoms 'improved'/'greatly improved') on treatment benefit scale, change from baseline in Kings Health Questionnaire (KHQ) domains, and AEs.

**Results:** The <40 group had the lowest CIC rate (1.1%) after onabotulinumtoxinA treatment, which increased slightly with age (3.2%, 5.3%, 5.3%, 7.2% in 40-49, 50-59, 60-69, and  $\ge$ 70

groups). Mean CIC duration was 3 days in the <40 group and 44-88 days in all other groups. All groups showed substantial %UI reduction (-46.8% to -64.4%). High proportions of patients achieved ≥50%UI reduction and treatment benefit. Improvements in KHQ domains were ~3-6x the minimally important difference. Urinary tract infection was the most common AE.

Conclusions: CIC risk in onabotulinumtoxinA-treated OAB patients was low in all groups, increasing slightly with age. All groups showed substantial UI reductions, QOL improvements and treatment benefit. OnabotulinumtoxinA was well-tolerated.