

# 32<sup>nd</sup> World Pediatrics Conference

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## Short and long-term efficacy and safety of pediatric prolonged-release melatonin for insomnia in children with autism spectrum disorder

and

<sup>1</sup>Yulius Academy, Netherlands

<sup>2</sup>Vanderbilt University Medical Center, USA

<sup>3</sup>Strasbourg University Hospital, France

<sup>4</sup>Neurim Pharmaceuticals Ltd, Israel

<sup>5</sup>Kennedy Krieger Institute, USA

<sup>6</sup>Johns Hopkins University, USA

<sup>7</sup>Evelina London Children's Hospital, Guy's and St Thomas, UK

**Objective:** To present results from an international multicenter study on the efficacy and safety of pediatric-appropriate prolonged release melatonin minitablets (Slenyto®) in children and adolescents with Autism Spectrum Disorders suffering from insomnia.

**Methods:** A 13 weeks double-blind placebo controlled study, followed by a prospective 9-month open-label follow-up study to test the efficacy and safety of Slenyto® in community dwelling patients with ASD suffering from sleep problems. Sleep measures included the validated caregivers' Sleep and Nap Diary (SND) and Composite Sleep Disturbance Index (CSDI) and additional measurements capturing child behavior (Strength and Difficulty Questionnaire, SDQ) and quality of life of parents (WHO-5).ance Index