

**LONG-TERM SAFETY OF METHYLPHENIDATE HYDROCHLORIDE MODIFIED RELEASE (MPH-LA) IN THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN ADULTS**Y. Ginsberg<sup>1</sup>, T. Tvedten<sup>2</sup>, T. Arngrim<sup>3</sup>, A. Philipsen<sup>4</sup>, P. Gandhi<sup>5</sup>, C.W. Chen<sup>6</sup>, V. Kumar<sup>6</sup>, M. Huss<sup>7</sup>

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**Introduction**

A previous 40-week, randomised, double-blind placebo-controlled core study [comprising of *dose confirmation* (9-week), *real-life dose optimisation* (5-week) and *maintenance of effect phases* (6-month)] reported the safety of MPH-LA in the treatment of adult ADHD. Here, we report the long-term safety from the extension phase (6-month) of this core study.

**Methods**

During the extension phase, patients initiated treatment with MPH-LA 20 mg/day; up-titrated to an optimal dose of 40, 60 or 80 mg/day in increments of 20 mg/week. Safety was analysed from *baseline of maintenance of effect phase* (core study); and from baseline of extension phase to end of extension phase. Adverse events (AEs) and serious adverse events (SAEs) were reported.

**Results**

Incidence of AEs occurring anytime starting from baseline of the *maintenance of effect phase* (core study) until the end of extension phase was 80.5%. The incidence of AEs occurring in the extension phase period was 69.8% (Table). Incidence of serious AEs (SAEs) reported during both periods were similar (0.7%). Most common AEs were nasopharyngitis, headache, decreased appetite, dry mouth and nausea. No deaths were reported. No new or unexpected results were observed for laboratory findings, vital signs or ECGs. None of the patients had QT, QTcB or QTcF  $\geq 500$ ms during the study.

**Conclusions**

Long-term treatment with MPH-LA in adult ADHD patients was well-tolerated.

Table: Number (%) of patients with most frequent AEs and SAEs		
	AEs occurring anytime starting from the baseline of <i>maintenance of effect phase</i> (core study) to the end of extension phase	AEs occurring anytime in the extension phase
(Preferred Term $\geq 5\%$ )		
	N=298 n (%)	N=298 n (%)
Total AEs	240 (80.5)	208 (69.8)
Nasopharyngitis	79 (26.5)	57 (19.1)
Headache	62 (20.8)	42 (14.1)
Decreased appetite	26 (8.7)	23 (7.7)
Dry mouth	24 (8.1)	20 (6.7)
Nausea	18 (6.0)	15 (5.0)
Upper respiratory tract infection	17 (5.7)	14 (4.7)
Diarrhoea	15 (5.0)	6 (2.0)
Total SAEs	2 (0.7)	2 (0.7)
Pancreatitis	1 (0.3)	1 (0.3)
Exostosis	1 (0.3)	1 (0.3)
Non-Hodgkin's lymphoma	1 (0.3)	1 (0.3)