

# **Supplementary Material**

Article Title: Symptomatic and Functional Response and Remission From the Open-Label Treatment-

Optimization Phase of a Study With DR/ER-MPH in Children With ADHD

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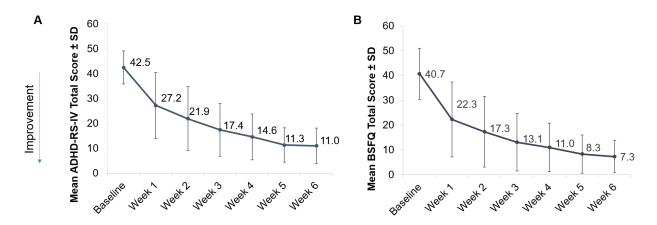
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### Supplementary Table 1. Symptom and Functional Impairment Assessments and Thresholds

	Early Morning Functional Impairment		Symptoms	Late Afternoon/Evening Functional Impairment
	BSFQ	PREMB-R AM	ADHD-RS-IV	PREMB-R PM
Scale description	Validated 20-item clinician-rated scale based on a structured parent interview assessing early morning functional impairment between the time of awakening and getting to school or other morning activities (ie, from 6:00 AM to 9:00 AM) in children with ADHD. <sup>32</sup>	Validated 3-item clinician-rated subscale based on structured parent interview assessing functional impairment during the early morning (eg, getting up and out of bed).33,34	Validated 18-item clinician-rated scale evaluating ADHD symptomology based on the DSM-IV diagnostic criteria for ADHD. <sup>35</sup>	Validated 8-item clinician-rated subscale based on structured parent interview assessing functional impairment during the late afternoon/evening (eg, doing/completing homework, getting to bed, and falling asleep).34
Scale scoring	Items rated from 0 (none) to 3 (severe); total scores range from 0 to 60. Scores reflected functional impairment over the preceding week. <sup>32</sup>	Items rated from 0 (none) to 3 (a lot); total scores range from 0 to 9. Scores reflected the last two school days prior to the study visit. 33,34	Items rated from 0 (no symptoms) to 3 (severe symptoms); total scores range from 0 to 54. Scores reflected symptoms over the preceding week. <sup>35</sup>	Items rated from 0 (none) to 3 (a lot); total scores range from 0 to 24. Scores reflected the last two school days prior to the study visit. <sup>34</sup>
Schedule	Assessed at each open- label visit; ≥33% improvement from baseline was required for randomization.	Assessed at the beginning and end of the 6-week openlabel phase as well as following one week of double-blind treatment, which was included as a secondary endpoint.	Assessed at each open- label visit; ≥33% improvement from baseline was required for randomization.	Assessed at the beginning and end of the 6-week open-label phase as well as following one week of double-blind treatment, which was included as a secondary endpoint.
Response threshold (anchored to CGI-I of 1 or 2)	Change from baseline of ≥45%. <sup>29</sup>	Change from baseline of ≥49%. <sup>29</sup>	Change from baseline of ≥40%. <sup>25</sup>	Change from baseline of ≥29%. <sup>29</sup>
Remission threshold (corresponding to less than screening risk)	≤24 for individuals 6–8 years of age and ≤21 for individuals 9–12 years of age. <sup>30</sup>	≤4 for individuals 6–8 years of age and ≤3 for individuals 9–12 years of age. <sup>30</sup>	Score ≤18. <sup>13</sup>	≤10 for individuals 6–8 years of age and ≤8 for individuals 9–12 years of age. <sup>30</sup>
Cut-offs for severity thresholds of temporal functional impairment <sup>30</sup> 6 –8 years 9–11 years 12–14 years 15–17 years	SR         Mild         Mod         Sev           80 <sup>th</sup> 90 <sup>th</sup> 93 <sup>rd</sup> 98 <sup>th</sup> 25         33         36         43           22         30         36         43           22         30         34         42           21         28         31         42	SR         Mild         Mod         Sev           80th         90th         93rd         98th           5         6         6         8           4         6         6         7           4         6         6         7           4         6         6         7		SR         Mild         Mod         Sev           80 <sup>th</sup> 90 <sup>th</sup> 93 <sup>rd</sup> 98 <sup>th</sup> 11         15         16         19           9         13         16         19           9         13         15         18           9         13         15         18

Abbreviations: ADHD, attention-deficit/hyperactivity disorder; ADHD-RS-IV, ADHD Rating Scale-IV; BSFQ, Before School Functioning Questionnaire; CGI-I, Clinical Global Impressions-Improvement; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> Edition; Mod, moderate; PREMB-R AM, Parent Rating of Evening and Morning Behavior, Revised, Morning subscale; PREMB-R PM, Parent Rating of Evening and Morning Behavior, Revised, Evening subscale; Sev, severe; SR, screening risk.

## Supplementary Figure 1. ADHD-RS-IV and BSFQ Scores with DR/ER-MPH Treatment



Note: Scores reflect symptoms and functional impairment over the preceding week. Therefore, baseline scores reflect the previous untreated week.

Abbreviations: ADHD-RS-IV, ADHD Rating Scale-IV; BSFQ, Before School Functioning Questionnaire; DR/ER-MPH, delayed-release and extended-release methylphenidate; SD, standard deviation.