Clinical Study Summary: Study B4Z-CA-LYCS

A Phase IIIb Open-label Trial of Atomoxetine Hydrochloride to Evaluate Academic Outcome in Children Ages 8 to 11 Years with Attention-Deficit/Hyperactivity Disorder

Date summary approved by Lilly: 26 June 2007

Brief Summary of Results

The primary objective of this 1-year, Phase 3b, multicenter, open-label study was to assess, in medication-naïve patients treated with atomoxetine, the correlation between change from baseline (premedicated) to 1 year in attention-deficit/hyperactivity disorder (ADHD) symptoms as measured by the Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored (ADHDRS-IV-Parent:Inv) total score, and change from baseline to 1 year in academic achievement as measured by the total of the composite scores of the Broad Reading, Broad Math, and Broad Written Language subtests of the Woodcock-Johnson Tests of Achievement® (WJ III®).

- A total of 105 patients were enrolled in the study, of which 83 (79.0%) patients completed Visit 9 (6 months), and 72 (68.6%) patients completed the study (1 year).

- The majority of patients were male (72.4%) and Caucasian (77.1%). The mean age was 9.3 years (95% CI: 9.2, 9.5). A total of 70.5% and 29.5% of patients were diagnosed with Combined and Inattentive subtypes of ADHD respectively.
- The correlation of change from baseline between ADHDRS-IV-Parent:Inv and WJ III for 1-year completers was -.066 and not statistically significant (p=.600). A negative correlation indicates agreement between both scales.

- The mean change from baseline in ADHDRS-IV-Parent:Inv for 1-year completers was -21.8 (n=66, 95% CI: -24.6, -18.9, p<.001), indicating an improvement.

- The mean increase in raw WJ III total composite score at 1 year was 37.6 (n=66, 95% CI: 32.3, 42.9, p<.001), indicating an improvement. In terms of subtests, improvements were demonstrated on all WJ III subtests in raw scores, with all changes from baseline statistically significant (p<.001). For patients completing the 6-month visit, correlation between Letter-Word Identification and ADHDRS-IV-Parent:Inv was -.296 (p=.011). Disagreement or nonsignificant correlations were observed for all other subitems.

- Improvements were observed in the raw scores of all Behavior Rating Inventory of Executive Function™ (BRIEF™) scales at 1 year. Correlations of .6 or greater were observed between the ADHDRS-IV-Parent:Inv and Global Executive Composite, Metacognition, and Behavioral Regulation indices. The correlations between ADHDRS-IV-Parent:Inv and each clinical scale were all statistically significant (p≤.05) and ranged from .392 to .645.

- Correlations between the Behavior Assessment System for Children (BASC) raw scores at 1 year and ADHDRS-IV-Parent:Inv were statistically significant (p≤.05) for most scales within the Parent Rating Scale-Child (PRS-C), with the exception of Somatization, Anxiety, and Leadership. For the Self-Report of Personality-Child (SRP-C), correlations with ADHDRS-IV-Parent:Inv were not statistically significant with the following exceptions: Attitude to School (r = -.329, p=.009), Attitude to Teachers (r = -.249, p=.049), and Relations with Parents (r = .283, p=.026).

- The mean change from baseline in the Weiss Functional Impairment Rating Scale-Parent Report (WFIRS-P) for 1-year completers was -0.42 (95% CI: -0.54, -0.31, p<.001). The correlation between improvement in ADHDRS-IV-Parent:Inv and improvement in WFIRS-P was .520 (p<.001).

- Symptom improvement observed with the ADHDRS-IV-Parent:Inv was in agreement with the Clinical Global Impressions-ADHD-Severity scale (CGI-ADHD-S), where the mean decrease in severity was 2.3 (95% CI: -2.6,-2.0, p<.001). The correlation between these two measures was .672 (p<.001).
- One serious adverse event, suicidal ideation, occurred at 6 months, which the investigator believed was possibly related to study medication. There were no deaths during this study. The most common treatment-emergent adverse events were decreased appetite, headache, vomiting, nausea, upper abdominal pain, and fatigue.
Title of Study: A Phase IIIb Open-label Trial of Atomoxetine Hydrochloride to Evaluate Academic Outcome in Children Ages 8 to 11 Years with Attention-Deficit/Hyperactivity Disorder.

Investigators: This multicenter study included 10 principal investigators.

Study Centers: This study was conducted at 10 study centers in one country.

Length of Study: 22 months
Date of first patient visit: 12 August 2004
Date of last patient visit: 29 June 2006

Phase of Development: 3b

Objectives: The primary objective of this study was to assess the correlation of change from baseline (premedicated) to 1 year in attention-deficit/hyperactivity disorder (ADHD) symptoms as measured by the Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored (ADHDRS-IV-Parent:Inv) total score (DuPaul et al. 1998; Faries et al. 2001) with change from baseline to 1 year in academic achievement as measured by the total of the Broad Reading, Broad Math, and Broad Written Language subtest composite scores of the Woodcock-Johnson Tests of Achievement® (WJ III®; Woodcock et al. 2000) in medication-naïve patients treated with atomoxetine. The secondary objectives of the study were as follows:

- To assess the correlation of change from baseline to 1 year, or study discontinuation, in ADHD symptoms as measured by the ADHDRS-IV-Parent:Inv with change from baseline in each of the academic achievement composite scores of the Broad Reading, Broad Math, and Broad Written Language subtests of the WJ III.
- To assess the change from baseline to endpoint in academic achievement of patients treated with atomoxetine as measured by the total of the composite scores of the Broad Reading, Broad Math, and Broad Written Language subtests of the WJ III.
- To assess the change from baseline to endpoint in academic achievement of patients treated with atomoxetine as assessed by the composite scores and the items in the composite scores (Broad Reading: letter word identification, reading fluency, passage comprehension; Broad Math: calculation, math fluency, applied problems; Broad Written Language: spelling, writing fluency, writing samples) of the WJ III.
- To assess change from baseline to 1 year, or study discontinuation, in executive functioning as assessed by the Behavior Rating Inventory of Executive Function™ (BRIEF™; Gioia et al. 2000).
- To assess the change from baseline to 1 year, or study discontinuation, in behavior and emotions as assessed by the Behavior Assessment System for Children (BASC; Reynolds and Kamphaus 1992) rating scales completed by the child’s parent and the child.
- To assess the efficacy of atomoxetine treatment on the core symptoms of ADHD by the change from baseline to 1 year, or study discontinuation, in the total score of the ADHDRS-IV-Parent:Inv and the Clinical Global Impressions-Attention-Deficit/Hyperactivity Disorder-Severity scale (CGI-ADHD-S; Guy 1976).
- To assess the relationships between change in core ADHD symptoms and change in functional outcome at home, at school, in social interactions, in activities of daily living and health, and in risk-taking and general well-being as assessed by the parent-completed questionnaire: Weiss Functional Impairment Rating Scale-Parent Report (WFIRS-P) at baseline and at 1 year, or at study discontinuation.
- To assess the relationships and inter-relationships between changes in the secondary objective measures and changes in core ADHD symptoms.

Study Design: This was a Phase 3b, multicenter, single-arm, 1-year, open-label study of atomoxetine in outpatients aged 8 to 11 years diagnosed with ADHD.
Number of Patients:
Planned: 100
Enrolled: 105
Completed: 72

Diagnosis and Main Criteria for Inclusion: Male or female outpatients of at least 8 years of age but less than 11 years of age at Visit 1, who met the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Text Revision™ (DSM-IV-TR™) criteria for ADHD and had a symptom severity threshold of at least 1.5 standard deviations above the age and gender norm for total score on the ADHDRS-IV-Parent:Inv. Patients were naïve to medications used to treat ADHD. Patients with current or past history of bipolar I or II disorder, psychosis, autism, Asperger’s syndrome, pervasive developmental disorder, conduct disorder, seizure disorder, or serious medical conditions were excluded.

Test Product, Dose, and Mode of Administration: Atomoxetine was initially administered for 7 days at 0.5 mg/kg/day as a single daily dose, followed by an increase to approximately 1.2 mg/kg/day. Investigators were allowed to adjust the atomoxetine dose between 0.8 mg/kg/day and 1.4 mg/kg/day based on efficacy and tolerability.

Duration of Treatment: 1 year

Variables:
**Efficacy:** Academic achievement was measured by WJ III. ADHD symptoms were assessed using ADHDRS-IV-Parent:Inv. The WJ III combined raw scores of the Broad Reading, Broad Math, and Broad Written Language subtests and the ADHDRS-IV-Parent:Inv total score were the primary outcome variables. The WJ III Broad Reading, Broad Math, and Broad Written Language subscores and the ADHDRS-IV-Parent:Inv Inattention and Hyperactivity-Impulsivity subscale scores were considered secondary outcomes variables.

Other secondary outcome variables were: BRIEF total and subscale scores, which measured executive functioning; BASC, which assessed a child’s behavior and feelings (both the parent rating scales [PRS-C] and self-report of personality [SRP-C] were used); CGI-ADHD-S, which assessed global severity of ADHD symptoms. WFIRS-P total and subscales measured the child’s functioning. In addition, raw scores, T-scores, and percentile rankings of the scales at baseline and endpoint were presented where available. When change from baseline was measured, only raw scores were used.

**Safety:** Assessment of adverse events and vital signs.

Evaluation Methods:
**Statistical:** The primary efficacy analysis utilized the Pearson’s correlation coefficient between the change from baseline to 1 year in ADHDRS-IV-Parent:Inv total score and the change from baseline to 1 year of the combined raw scores of the Broad Reading, Broad Math, and Broad Written Language subtests of the WJ III. The primary analysis population was 1-year completers. For secondary analyses, any change from baseline analyses were performed using both 1-year completers and patients completing the 6-month visit who were still on study medication. When the 1-year visit was missing; a last observation carried forward approach was used. Summary statistics were computed on change scores including mean, median, standard deviation, and the two-sided 95% confidence interval. Change from baseline was tested using a paired t-test or Wilcoxon signed rank test at two-sided alpha of 0.05.
Study Design:

The schematic displayed in Figure 1 represents the study design.

![Study design diagram]

Figure 1. Study design.

Results:

**Patient Characteristics**

Table 1 summarizes the baseline characteristics of all patients enrolled in this study.
Table 1. Patient Characteristics at Baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=105</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (95% CI)</td>
<td>9.3 (9.2, 9.5)</td>
</tr>
<tr>
<td>Gender [n (%)]</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>76 (72.4)</td>
</tr>
<tr>
<td>Female</td>
<td>29 (27.6)</td>
</tr>
<tr>
<td>Race [n (%)]</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>81 (77.1)</td>
</tr>
<tr>
<td>African Descent</td>
<td>5 (4.8)</td>
</tr>
<tr>
<td>East Asian</td>
<td>4 (3.8)</td>
</tr>
<tr>
<td>Western Asian</td>
<td>5 (4.8)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (9.5)</td>
</tr>
<tr>
<td>Education, current grade [n (%)]</td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>15 (14.3)</td>
</tr>
<tr>
<td>Grade 3</td>
<td>28 (26.7)</td>
</tr>
<tr>
<td>Grade 4</td>
<td>39 (37.1)</td>
</tr>
<tr>
<td>Grade 5</td>
<td>22 (21.0)</td>
</tr>
<tr>
<td>Grade 6</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>ADHD Subtype [n (%)]</td>
<td></td>
</tr>
<tr>
<td>Inattentive</td>
<td>31 (29.5)</td>
</tr>
<tr>
<td>Combined</td>
<td>74 (70.5)</td>
</tr>
</tbody>
</table>

Abbreviations: ADHD = attention-deficit/hyperactivity disorder; n = number of patients; N = total number of patients.

Patient Disposition

A total of 105 patients were enrolled in the study. Of these, 72 patients (68.6%) completed the study and 33 patients (31.4%) discontinued early. Table 2 displays a summary of the reasons for discontinuation.

Table 2. Reasons for Discontinuation

<table>
<thead>
<tr>
<th>Reason for Discontinuation [n (%)]</th>
<th>N=105</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse event</td>
<td>6 (5.7)</td>
</tr>
<tr>
<td>Lack of efficacy, patient/caregiver perception</td>
<td>3 (2.9)</td>
</tr>
<tr>
<td>Lack of efficacy, physician perception</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Lack of efficacy, patient/caregiver and physician perception</td>
<td>10 (9.5)</td>
</tr>
<tr>
<td>Personal conflict or other patient/caregiver decision</td>
<td>4 (3.8)</td>
</tr>
<tr>
<td>Protocol violation</td>
<td>6 (5.7)</td>
</tr>
<tr>
<td>Lost to follow up</td>
<td>3 (2.9)</td>
</tr>
</tbody>
</table>

Abbreviations: n = number of patients; N = total number of patients.
**Primary Outcome Measure**

Among 1-year completers, the correlation of change from baseline between the Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored (ADHDRS-IV-Parent:Inv) and the Woodcock-Johnson Tests of Achievement (WJ III) was -.066 and not statistically significant (p=.600; Table 3). An increase in WJ III score indicates an improvement. A negative correlation indicates agreement between both scales.
### Table 3. Change in WJ III Total Composite Score and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 12 (1 Year)

<table>
<thead>
<tr>
<th></th>
<th>Baseline Score</th>
<th>Endpoin Score</th>
<th>Change from Baseline to Endpoint Score</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>95% CI</th>
<th>p-value²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min,</td>
<td>Max,</td>
<td>Median</td>
<td>N</td>
</tr>
<tr>
<td>WJ III total of the</td>
<td>66</td>
<td>241.1 (7.90)</td>
<td>81,</td>
<td>393,</td>
<td>241</td>
<td>66</td>
</tr>
<tr>
<td>composite scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean; WJ III = Woodcock-Johnson Tests of Achievement.

¹ p-value using paired t-test comparing the mean change in the total of the composite scores of the WJ III to zero for patients completing Visit 12.
² p-value comparing the correlation between the change in ADHDRS-IV-Parent:Inv and the change in the total of the composite scores of the WJ III to zero for patients completing Visit 12.
**Secondary Outcome Measures**

The correlations of change from baseline to 6 months and 1 year in ADHD symptoms measured by the ADHDRS-IV-Parent:Inv with composite scores of the Broad Reading, Broad Math, and Broad Written Language subtests of the WJ III are summarized in Table 4 and Table 5, respectively.

The changes from baseline to 6 months or later, and 1 year in Behavior Rating Inventory of Executive Function™ (BRIEF™) overall and subscale scores are summarized in Table 6 and Table 7, respectively. A decrease in raw score indicates improvement. See Table 6 and Table 7 for the correlations between change in BRIEF and change in ADHDRS-IV-Parent:Inv.

The changes from baseline to 6 months or later, and 1 year in each of the subscales of the Behavior Assessment System for Children (BASC) are summarized in Table 8 and Table 9, respectively. A decrease on a clinical scale or an increase on an adaptive scale indicates improvement. See Table 8 and Table 9 for the correlations between change in BASC and change in ADHDRS-IV-Parent:Inv.

The changes from baseline to 6 months or later, and 1 year in the ADHDRS-IV-Parent:Inv (Table 10 and Table 11) and the Clinical Global Impressions-Attention-Deficit/Hyperactivity Disorder-Severity scale (CGI-ADHD-S; Table 12 and Table 13) scores are summarized. A decrease in score indicates an improvement. See Table 12 and Table 13 for the correlations between change in CGI-ADHD-S and change in ADHDRS-IV-Parent:Inv.

The changes from baseline to 6 months or later, and 1 year in total and subscale scores of the Weiss Functional Impairment Rating Scale-Parent Report (WFIRS-P) are summarized in Table 14 and Table 15, respectively. A decrease in score indicates an improvement. The correlations between changes in the WFIRS-P and change in ADHDRS-IV-Parent:Inv total score are summarized in Table 14 and Table 15.
Table 4. Change in WJ III Raw Scores (Subscales and Subtests) and Correlation with Change in ADHDRS-IV-Parent: Inv for Patients who Completed Visit 9 (6 Months) or Later

<table>
<thead>
<tr>
<th>WJ III ® Subscale or Subtest</th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>Correlation with Change in ADHD RS-IV-Parent: Inv</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
<th>95% CI</th>
<th>p-value&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broad Reading, total</td>
<td>99.9 (3.55)</td>
<td>113.4 (3.24)</td>
<td>13.5 (1.33)</td>
<td>&lt;.0001</td>
<td>-1.11 (10.8)</td>
<td>6.3</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Letter Word Identification</td>
<td>44.9 (1.27)</td>
<td>49.3 (1.11)</td>
<td>4.3 (0.52)</td>
<td>.0001</td>
<td>-0.19 (4.3)</td>
<td></td>
<td>.0110</td>
</tr>
<tr>
<td>Reading Fluency</td>
<td>31.0 (1.77)</td>
<td>37.5 (1.80)</td>
<td>6.5 (0.93)</td>
<td>.0001</td>
<td>-0.19 (4.7)</td>
<td></td>
<td>.0099</td>
</tr>
<tr>
<td>Passage Comprehension</td>
<td>24.0 (0.72)</td>
<td>26.6 (0.61)</td>
<td>2.6 (0.51)</td>
<td>&lt;.0001</td>
<td>-0.18 (2)</td>
<td></td>
<td>.5306</td>
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<tr>
<td>Broad Math, total</td>
<td>80.3 (2.50)</td>
<td>94.4 (2.76)</td>
<td>14.1 (1.23)</td>
<td>.0001</td>
<td>-0.11 (16.5)</td>
<td></td>
<td>.7991</td>
</tr>
<tr>
<td>Calculation</td>
<td>13.5 (0.44)</td>
<td>15.5 (0.42)</td>
<td>2.0 (0.32)</td>
<td>&lt;.0001</td>
<td>-0.08 (2.6)</td>
<td></td>
<td>.0227</td>
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<tr>
<td>Math Fluency</td>
<td>36.4 (1.77)</td>
<td>44.5 (2.00)</td>
<td>8.0 (1.10)</td>
<td>&lt;.0001</td>
<td>-0.19 (5.8)</td>
<td></td>
<td>.4647</td>
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<tr>
<td>Applied Problems</td>
<td>30.4 (0.58)</td>
<td>34.4 (0.70)</td>
<td>4.1 (0.49)</td>
<td>&lt;.0001</td>
<td>-0.13 (3.1)</td>
<td></td>
<td>.6452</td>
</tr>
<tr>
<td>Broad Written Language, total</td>
<td>62.2 (2.00)</td>
<td>69.8 (2.09)</td>
<td>7.6 (1.07)</td>
<td>&lt;.0001</td>
<td>-0.12 (7.8)</td>
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<td>.6866</td>
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<td>Spelling</td>
<td>27.4 (0.83)</td>
<td>30.2 (0.87)</td>
<td>2.7 (0.43)</td>
<td>&lt;.0001</td>
<td>-0.08 (3.6)</td>
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<td>.6628</td>
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<tr>
<td>Writing Fluency</td>
<td>12.4 (0.68)</td>
<td>14.9 (0.72)</td>
<td>2.5 (0.55)</td>
<td>&lt;.0001</td>
<td>-0.24 (3)</td>
<td></td>
<td>.8715</td>
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<td>Writing Samples</td>
<td>22.4 (0.77)</td>
<td>25.1 (0.71)</td>
<td>2.6 (0.58)</td>
<td>&lt;.0001</td>
<td>-0.14 (3.8)</td>
<td></td>
<td>.4800</td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent: Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean; WJ III = Woodcock-Johnson Tests of Achievement.

1 p-value using a paired t-test or Wilcoxon signed rank test comparing the mean change in subscale or subtest score of the WJ III to zero for patients completing Visit 9 or later.

2 p-value comparing the correlation between the change in ADHDRS-IV-Parent: Inv and the change in subscale or subtest score of the WJ III to zero for patients completing Visit 9 or later.
### Table 5. Change in WJ III Raw Scores (Subscales and Subtests) and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 12 (1 Year)

<table>
<thead>
<tr>
<th>WJ III Subscale or Subtest</th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
<th>95% CI</th>
<th>p-value&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
<td>Min, Max, Median</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
</tr>
<tr>
<td>Broad Reading, total</td>
<td>98.6 (3.77)</td>
<td>91.1, 106.1</td>
<td></td>
<td></td>
<td>113.7 (3.44)</td>
<td>106.8, 120.6</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Letter-Word Identification</td>
<td>44.0 (1.31)</td>
<td>41.8, 46.8</td>
<td></td>
<td></td>
<td>49.2 (1.17)</td>
<td>46.8, 51.5</td>
<td>-.105</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Reading Fluency</td>
<td>30.4 (1.91)</td>
<td>26.6, 34.2</td>
<td></td>
<td></td>
<td>37.8 (1.90)</td>
<td>34.0, 41.6</td>
<td>-.102</td>
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<td></td>
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<td>&lt;.0001</td>
</tr>
<tr>
<td>Passage Comprehension</td>
<td>24.0 (0.77)</td>
<td>22.5, 25.5</td>
<td></td>
<td></td>
<td>26.7 (0.66)</td>
<td>25.4, 28.1</td>
<td>-.100</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Broad Math, total</td>
<td>81.0 (2.67)</td>
<td>75.7, 86.3</td>
<td></td>
<td></td>
<td>95.0 (2.80)</td>
<td>89.4, 100.6</td>
<td>-.096</td>
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<td>-.028</td>
</tr>
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<td>Calculation</td>
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<td>13.0, 14.7</td>
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<td></td>
<td>15.5 (0.45)</td>
<td>14.6, 16.4</td>
<td>-.096</td>
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<td></td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Math Fluency</td>
<td>36.7 (1.93)</td>
<td>32.8, 40.5</td>
<td></td>
<td></td>
<td>44.7 (2.09)</td>
<td>40.5, 46.6</td>
<td>-.091</td>
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<td>&lt;.0001</td>
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<td>Applied Problems</td>
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<td>29.3, 31.7</td>
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<td>34.8 (0.66)</td>
<td>33.6, 36.2</td>
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<td>Broad Written Language, total</td>
<td>61.5 (2.13)</td>
<td>57.2, 64.7</td>
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<td>70.0 (2.30)</td>
<td>65.5, 74.4</td>
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<td>Spelling</td>
<td>27.1 (0.90)</td>
<td>25.3, 28.9</td>
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<td>30.0 (0.96)</td>
<td>28.1, 32.0</td>
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<tr>
<td>Writing Fluency</td>
<td>12.0 (0.71)</td>
<td>10.6, 12.3</td>
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<td>14.9 (0.74)</td>
<td>13.3, 16.3</td>
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<tr>
<td>Writing Samples</td>
<td>22.3 (0.81)</td>
<td>20.7, 24.0</td>
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<td>25.5 (0.76)</td>
<td>23.9, 27.0</td>
<td>-.076</td>
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Abbreviations: ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean; WJ III = Woodcock-Johnson Tests of Achievement.

1 p-value using a paired t-test or Wilcoxon signed rank test comparing the mean change in subscale or subtest score of the WJ III to zero for patients completing Visit 12.

2 p-value comparing the correlation between the change in ADHDRS-IV-Parent:Inv and the change subscale or subtest score of the WJ III to zero for patients completing Visit 12.
## Table 6. Change in BRIEF Global Executive Composite and Subscale Scores and Correlation with Change in ADHRS-IV-Parent:Inv for Patients who Completed Visit 9 (6 Months) or Later

<table>
<thead>
<tr>
<th></th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Endpoint Percentile Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>p-value 1</th>
<th>Correlation with Change in ADHRS-IV-Parent:Inv</th>
<th>95% CI</th>
<th>p-value 2</th>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max</td>
<td>95% CI</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Overall: Global Executive Composite</td>
<td>73</td>
<td>169.5 (2.34)</td>
<td>130, (164.8, 174.1)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max</td>
<td>95% CI</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Behavioral Regulation</td>
<td>73</td>
<td>60.6 (1.29)</td>
<td>39.83, (58.1, 63.2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max</td>
<td>95% CI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metacognition</td>
<td>73</td>
<td>108.8 (1.39)</td>
<td>79, (106.0, 111.6)</td>
<td></td>
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</tr>
</tbody>
</table>

Abbreviations: ADHRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version; Investigator Administered and Scored; BRIEF = Behavior Rating Inventory of Executive Function; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

1 p-value using a paired t-test or Wilcoxon signed rank test comparing the mean change in BRIEF Global Executive Composite and subscale scores to zero for patients completing Visit 9 or later.

2 p-value comparing the correlation between change in ADHRS-IV-Parent:Inv and change in the BRIEF Global Executive Composite and subscale scores to zero for patients completing Visit 9 or later.
## Table 7.
Change in BRIEF Global Executive Composite and Subscale Scores and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 12 (1 Year)

<table>
<thead>
<tr>
<th></th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Endpoint Percentile Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>p-value 1</th>
<th>p-value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall: Global</td>
<td>168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Executive Composite</td>
<td>213. (245)</td>
<td>82. (144.7)</td>
<td>82 (144.7)</td>
<td>-27 (23.9)</td>
<td>0.793</td>
<td></td>
</tr>
<tr>
<td>Behavioral</td>
<td>66  60.4 (57.7)</td>
<td>33. (45.9)</td>
<td>66  6.99 (59.4)</td>
<td>-11.5 (-14.1)</td>
<td>0.607</td>
<td>0.001</td>
</tr>
<tr>
<td>Regulation</td>
<td>66  61 (63.1)</td>
<td>48. (51.9)</td>
<td>66  72 (73.3)</td>
<td>(1.26) -12</td>
<td>0.773</td>
<td></td>
</tr>
<tr>
<td>Metacognition</td>
<td>66  105.2 (130.0)</td>
<td>50. (85.0)</td>
<td>66  86 (80.9)</td>
<td>-18.9 (-23.4)</td>
<td>0.064</td>
<td>0.001</td>
</tr>
<tr>
<td>Inhibit</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Shift</td>
<td>66  60 (63.1)</td>
<td>48. (51.9)</td>
<td>66  72 (73.3)</td>
<td>(1.26) -12</td>
<td>0.773</td>
<td></td>
</tr>
<tr>
<td>Emotional</td>
<td>66  105.2 (130.0)</td>
<td>50. (85.0)</td>
<td>66  86 (80.9)</td>
<td>-18.9 (-23.4)</td>
<td>0.064</td>
<td>0.001</td>
</tr>
<tr>
<td>Control</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Initiate</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Working</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Memory</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Plan/Organize</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Organization of Materia</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Monitor</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Inconsistency</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
<tr>
<td>Negativity</td>
<td>66  168.5 (163.6)</td>
<td>128. (131.5)</td>
<td>66  73.1 (79.5)</td>
<td>-30.4 (-79.3)</td>
<td>0.664</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; BRIEF = Behavior Rating Inventory of Executive Function; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

1 p-value using a paired t-test or Wilcoxon signed rank test comparing the mean change in BRIEF Global Executive Composite and subscale scores to zero for patients completing Visit 12.

2 p-value comparing the correlation between change in ADHDRS-IV-Parent:Inv and change in BRIEF Global Executive Composite and subscale scores to zero for patients completing Visit 12.
## Table 8. Change in BASC (Parent and Child Version) Subscales and Correlation with Change in ADHDRS-IV Parent:Inv for Patients who Completed Visit 9 (6 Months) or Later

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>Correlation with Change in ADHDRS-IV Parent:Inv</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
<th>95% CI</th>
<th>p-value&lt;sup&gt;2&lt;/sup&gt;</th>
<th>95% CI</th>
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<td><strong>Baseline Raw Score</strong></td>
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<td></td>
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<tr>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
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<tr>
<td><strong>Clinical Self-Report</strong></td>
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</tr>
<tr>
<td>Attitude to School</td>
<td>72</td>
<td>4.4</td>
<td>0, 9, 4 (3.7, 5.1)</td>
<td></td>
<td>0.0037</td>
<td>-264</td>
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<td>(0.36)</td>
<td>(0.37)</td>
<td>(0.37)</td>
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<tr>
<td>Attitude to Teachers</td>
<td>72</td>
<td>3.0</td>
<td>0, 10, 2 (2.3, 3.6)</td>
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<td>-0.264</td>
<td>(0.31)</td>
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<td>(0.28)</td>
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<td>Atypicality</td>
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<td>0, 14, 6 (5.2, 6.9)</td>
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<td>Locus of Control</td>
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<td>Anxiety</td>
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<td>Sense of Inadequacy</td>
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<td>1, 11, 4 (3.9, 5.1)</td>
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<td><strong>Adaptive Scales</strong></td>
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<td>Relations with Parents</td>
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<td>Interpersonal Relations</td>
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<td>7.7</td>
<td>0, 10, 9 (7.0, 8.3)</td>
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<td>(0.31)</td>
<td>(0.31)</td>
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<td>Self-Esteem</td>
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<td>0, 6, 6 (4.4, 4.7)</td>
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<td>(0.18)</td>
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<td>Self-Reliance</td>
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<td>1, 14, 8 (8.9, 10.4)</td>
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<td>(0.33)</td>
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</table>

(continued)
<table>
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<tr>
<th>Clinical Scales</th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Endpoint T-Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>Correlation with Change in ADHDRS-Parent:Inv</th>
<th>p-value¹</th>
<th>95% CI</th>
<th>p-value²</th>
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</thead>
<tbody>
<tr>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
</tr>
<tr>
<td>Hyperactivity</td>
<td>73</td>
<td>14.4 (0.64)</td>
<td>5.29, (13.1)</td>
<td>8.2 (0.53)</td>
<td>0.22, (7.2)</td>
<td>73</td>
<td>52.4 (1.43)</td>
<td>30.89, (49.6)</td>
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<tr>
<td>Aggression</td>
<td>73</td>
<td>14.0 (0.72)</td>
<td>2.30, (12.5)</td>
<td>10.5 (0.65)</td>
<td>1.24, (9.2)</td>
<td>73</td>
<td>54.1 (1.48)</td>
<td>32.85, (51.1)</td>
</tr>
<tr>
<td>Conduct Problems</td>
<td>73</td>
<td>7.4 (0.53)</td>
<td>0.17, (6.4)</td>
<td>5.4 (0.45)</td>
<td>0.17, (4.5)</td>
<td>73</td>
<td>57.7 (1.73)</td>
<td>37, (54.2)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>73</td>
<td>11.9 (0.61)</td>
<td>0.26, (10.7)</td>
<td>9.7 (0.63)</td>
<td>1.26, (8.6)</td>
<td>73</td>
<td>47.8 (1.31)</td>
<td>29.82, (45.2)</td>
</tr>
<tr>
<td>Depression</td>
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<td>11.9 (0.75)</td>
<td>0.34, (10.4)</td>
<td>8.4 (0.62)</td>
<td>0.22, (7.1)</td>
<td>73</td>
<td>53.7 (1.47)</td>
<td>34.86, (50.8)</td>
</tr>
<tr>
<td>Somatization</td>
<td>73</td>
<td>4.2 (0.35)</td>
<td>0.13, (3.5)</td>
<td>4.0 (0.34)</td>
<td>0.12, (3.3)</td>
<td>73</td>
<td>47.3 (0.99)</td>
<td>36.7, (45.3)</td>
</tr>
<tr>
<td>Atypicality</td>
<td>73</td>
<td>5.8 (0.47)</td>
<td>0.19, (4.9)</td>
<td>3.2 (0.30)</td>
<td>0.13, (2.6)</td>
<td>73</td>
<td>51.3 (1.19)</td>
<td>38.93, (48.8)</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>73</td>
<td>5.6 (0.46)</td>
<td>0.16, (4.7)</td>
<td>4.6 (0.38)</td>
<td>0.15, (3.9)</td>
<td>73</td>
<td>49.2 (1.19)</td>
<td>35.82, (46.9)</td>
</tr>
<tr>
<td>Attention</td>
<td>73</td>
<td>15.2 (0.28)</td>
<td>10.21, (14.7)</td>
<td>11.5 (0.37)</td>
<td>2.18, (10.7)</td>
<td>73</td>
<td>61.6 (0.97)</td>
<td>37.79, (59.7)</td>
</tr>
<tr>
<td>Adaptability</td>
<td>73</td>
<td>9.7 (0.37)</td>
<td>1.20, (8.9)</td>
<td>11.4 (0.40)</td>
<td>5.29, (10.6)</td>
<td>73</td>
<td>42.7 (1.11)</td>
<td>25.67, (40.4)</td>
</tr>
<tr>
<td>Social Skills</td>
<td>73</td>
<td>19.6 (0.76)</td>
<td>5.39, (18.1)</td>
<td>22.2 (0.80)</td>
<td>6.38, (20.6)</td>
<td>73</td>
<td>44.4 (1.13)</td>
<td>24.67, (42.1)</td>
</tr>
<tr>
<td>Leadership</td>
<td>73</td>
<td>14.7 (0.49)</td>
<td>7.27, (15.3)</td>
<td>15.2 (0.56)</td>
<td>5.27, (14.1)</td>
<td>73</td>
<td>42.9 (1.02)</td>
<td>25.64, (40.9)</td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; BASC = Behavior Assessment System for Children; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

1 p-value using a paired t-test or Wilcoxon signed rank test comparing the mean change in BASC (parent and child version) subscale scores to zero for patients completing Visit 9 or later.

2 p-value comparing the correlation between change in ADHDRS-IV-Parent:Inv and change in BASC (parent and child version) subscale scores to zero for patients completing Visit 9 or later.
### Table 9. Change in BASC (Parent and Child Version) Subscales and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 12 (1 Year)

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>p-value¹</th>
<th>p-value²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Min, Max</td>
<td>95% CI</td>
<td>Mean (SD)</td>
<td>Min, Max</td>
<td>95% CI</td>
</tr>
<tr>
<td><strong>Parent:Inv</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attitude to School</td>
<td>65</td>
<td>4.1 (0.37)</td>
<td>0, 9, 4</td>
<td>3.1 (0.37)</td>
<td>0, 9, 2</td>
<td>2.4 (3.9)</td>
</tr>
<tr>
<td>Attitude to Teachers</td>
<td>65</td>
<td>2.8 (0.34)</td>
<td>0, 10, 2</td>
<td>1.8 (0.27)</td>
<td>0, 9.1</td>
<td>1.2 (2.3)</td>
</tr>
<tr>
<td>Atypicality</td>
<td>65</td>
<td>6.1 (0.41)</td>
<td>0, 13, 6</td>
<td>4.4 (0.44)</td>
<td>0, 14.4</td>
<td>3.5 (5.3)</td>
</tr>
<tr>
<td>Locus of Control</td>
<td>64</td>
<td>6.7 (0.45)</td>
<td>0, 16, 7</td>
<td>5.6 (0.52)</td>
<td>0, 16.4</td>
<td>6.0 (5.9)</td>
</tr>
<tr>
<td>Social Stress</td>
<td>65</td>
<td>5.0 (0.37)</td>
<td>0, 12, 5</td>
<td>3.4 (0.35)</td>
<td>0, 12.3</td>
<td>2.7 (4.1)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>65</td>
<td>7.9 (0.58)</td>
<td>0, 17, 8</td>
<td>5.6 (0.57)</td>
<td>0, 17.5</td>
<td>4.4 (6.7)</td>
</tr>
<tr>
<td>Depression</td>
<td>65</td>
<td>5.1 (0.55)</td>
<td>0, 17, 4</td>
<td>3.1 (0.48)</td>
<td>0, 16.2</td>
<td>2.2 (4.1)</td>
</tr>
<tr>
<td>Sense of Inadequacy</td>
<td>65</td>
<td>4.4 (0.31)</td>
<td>3, 11, 4</td>
<td>2.8 (0.33)</td>
<td>0, 10.2</td>
<td>2.1 (3.4)</td>
</tr>
<tr>
<td><strong>Adaptive Scales:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relations with Parents</td>
<td>65</td>
<td>8.6 (0.24)</td>
<td>1, 10, 9</td>
<td>8.8 (9.0)</td>
<td>2, 10.9</td>
<td>8.4 (9.2)</td>
</tr>
<tr>
<td>Interpersonal Relations</td>
<td>65</td>
<td>7.6 (0.35)</td>
<td>0, 10, 9</td>
<td>8.3 (8.3)</td>
<td>2, 10</td>
<td>7.9 (9.1)</td>
</tr>
<tr>
<td>Self-Esteem</td>
<td>65</td>
<td>4.8 (0.20)</td>
<td>0, 6, 6</td>
<td>5.2 (0.17)</td>
<td>0, 6.6</td>
<td>4.9 (5.6)</td>
</tr>
<tr>
<td>Self-Reliance</td>
<td>65</td>
<td>9.8 (0.38)</td>
<td>1, 14, 9</td>
<td>10.9 (10.5)</td>
<td>11.4 (11.5)</td>
<td>10.3 (11.8)</td>
</tr>
</tbody>
</table>

(continued)
### Table 9. Change in BASC (Parent and Child Version) Subscales and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 12 (1 Year) (Concluded)

<table>
<thead>
<tr>
<th>BASC - Parent Rating Clinical Scales</th>
<th>Baseline Raw Score</th>
<th>Endpoint Raw Score</th>
<th>Endpoint T-Score</th>
<th>Change in Raw Score from Baseline to Endpoint</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>95% CI</th>
<th>p-value 1</th>
<th>95% CI</th>
<th>p-value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>N Mean (SD) Min, Max</td>
<td>N Mean (SD) Min, Max</td>
<td>N Mean (SD) Min, Max</td>
<td>N Mean (SD) Min, Max</td>
<td>Median 95% CI</td>
<td>N Mean (SD) Min, Max</td>
<td>N Mean (SD) Min, Max</td>
<td>Median 95% CI</td>
<td>Median 95% CI</td>
<td>Median 95% CI</td>
</tr>
<tr>
<td><strong>Hyperactivity</strong></td>
<td>66</td>
<td>14.3 (0.68)</td>
<td>3.29</td>
<td>(12.9, 15.6)</td>
<td>66</td>
<td>8.1 (0.58)</td>
<td>0.22</td>
<td>(6.9, 9.2)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Aggression</strong></td>
<td>66</td>
<td>13.6 (0.79)</td>
<td>2.30</td>
<td>(12.1, 15.2)</td>
<td>66</td>
<td>10.2 (0.67)</td>
<td>1.24</td>
<td>(8.9, 11.5)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Conduct Problems</strong></td>
<td>66</td>
<td>7.3 (0.54)</td>
<td>0.17</td>
<td>(6.2, 8.4)</td>
<td>66</td>
<td>5.2 (0.46)</td>
<td>0.14</td>
<td>(4.2, 6.1)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td>66</td>
<td>11.9 (0.66)</td>
<td>0.26</td>
<td>(10.5, 13.2)</td>
<td>66</td>
<td>9.7 (0.65)</td>
<td>1.26</td>
<td>(8.4, 11.0)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td>66</td>
<td>12.1 (0.81)</td>
<td>0.34</td>
<td>(10.5, 13.7)</td>
<td>66</td>
<td>8.2 (0.63)</td>
<td>0.22</td>
<td>(6.9, 9.4)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Somatization</strong></td>
<td>66</td>
<td>4.2 (0.40)</td>
<td>0.13</td>
<td>(3.4, 5.0)</td>
<td>66</td>
<td>4.0 (0.34)</td>
<td>0.12</td>
<td>(3.3, 4.7)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Atypicality</strong></td>
<td>66</td>
<td>6.2 (0.50)</td>
<td>0.19</td>
<td>(5.2, 7.2)</td>
<td>66</td>
<td>3.5 (0.33)</td>
<td>0.13</td>
<td>(2.8, 4.2)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Withdrawal</strong></td>
<td>66</td>
<td>5.6 (0.46)</td>
<td>0.16</td>
<td>(4.7, 6.5)</td>
<td>66</td>
<td>4.5 (0.36)</td>
<td>0.15</td>
<td>(3.8, 5.2)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Attention Problems</strong></td>
<td>66</td>
<td>15.3 (0.30)</td>
<td>10.21</td>
<td>(14.7, 15.9)</td>
<td>66</td>
<td>11.2 (0.40)</td>
<td>2.18</td>
<td>(10.4, 12.0)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Adaptability</strong></td>
<td>66</td>
<td>9.6 (0.38)</td>
<td>1.20</td>
<td>(8.8, 10.4)</td>
<td>66</td>
<td>11.4 (0.40)</td>
<td>5.20</td>
<td>(10.6, 12.2)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Social Skills</strong></td>
<td>66</td>
<td>19.7 (0.79)</td>
<td>5.39</td>
<td>(18.1, 21.2)</td>
<td>66</td>
<td>22.7 (0.81)</td>
<td>11.38</td>
<td>(21.0, 24.3)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Leadership</strong></td>
<td>66</td>
<td>15.0 (0.50)</td>
<td>7.07</td>
<td>(14.1, 16.5)</td>
<td>66</td>
<td>15.5 (0.57)</td>
<td>5.27</td>
<td>(14.4, 16.6)</td>
<td>66</td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; BASC = Behavior Assessment System for Children; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

1 p-value using a paired t-test or Wilcoxon signed rank test comparing the mean change in BASC (parent and child version) subscale scores to zero for patients completing Visit 12.

2 p-value comparing the correlation between change in ADHDRS-IV-Parent:Inv and change in BASC (parent and child version) subscale scores to zero for patients completing Visit 12.
## Table 10. Change in ADHDRS-IV-Parent:Inv Scores for Patients who Completed Visit 9 (6 Months) or Later

<table>
<thead>
<tr>
<th>ADHDRS-IV-Parent:Inv Scores</th>
<th>Baseline Score, Mean (SD), Median, Min, Max, 95% CI</th>
<th>Change Score, Mean (SD), Median, Min, Max, 95% CI</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD Rating Scale-IV:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent Version - Investigator Scored:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td>Baseline N: 75, 37.9 (0.88), 38, 16, 54, (36.2, 39.7)</td>
<td>Change N: 75, -20.9 (1.27), -22, -45, 3, (-23.5, -18.4)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Subscale Scores:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inattention</td>
<td>Baseline N: 75, 21.3 (0.42), 21, 11, 27, (20.4, 22.1)</td>
<td>Change N: 75, -11.0 (0.73), -11, -26, 5, (-12.5, -9.6)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Hyperactive/Impulsive</td>
<td>Baseline N: 75, 16.6 (0.70), 17, 5, 27, (15.2, 18.0)</td>
<td>Change N: 75, -9.9 (0.71), -9, -25, 3, (-11.3, -8.5)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

**Abbreviations:** ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

<sup>1</sup> p-value using a paired t-test comparing the mean change in ADHDRS-IV-Parent:Inv score to zero for patients completing Visit 9 or later.

## Table 11. Change in ADHDRS-IV-Parent:Inv Scores for Patients who Completed Visit 12 (1 Year)

<table>
<thead>
<tr>
<th>ADHDRS-IV-Parent:Inv Scores</th>
<th>Baseline Score, Mean (SD), Median, Min, Max, 95% CI</th>
<th>Change Score, Mean (SD), Median, Min, Max, 95% CI</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD Rating Scale-IV:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent Version - Investigator Scored:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td>Baseline N: 66, 37.6 (1.01), 38, 15, 54, (35.6, 39.6)</td>
<td>Change N: 66, -21.8 (1.43), -22, -47, 4, (-24.6, -18.9)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Subscale Scores:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inattention</td>
<td>Baseline N: 66, 21.0 (0.49), 21, 10, 27, (20.1, 22.0)</td>
<td>Change N: 66, -11.4 (0.79), -12, -26, 3, (-13.0, -9.8)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Hyperactive/Impulsive</td>
<td>Baseline N: 66, 16.6 (0.78), 17, 5, 27, (15.0, 18.1)</td>
<td>Change N: 66, -10.4 (0.82), -9, -26, 3, (-12.0, -8.8)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

**Abbreviations:** ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

<sup>1</sup> p-value using a paired t-test comparing the mean change in ADHDRS-IV-Parent:Inv score to zero for patients completing Visit 12.
### Table 12. Change in CGI-ADHD-S and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 9 (6 Months) or Later

<table>
<thead>
<tr>
<th>Baseline Score</th>
<th>Endpoint Score</th>
<th>Change from Baseline to Endpoint</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>95% CI</th>
<th>P-value¹</th>
<th>95% CI</th>
<th>P-value²</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGI-ADHD-S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
</tr>
<tr>
<td>75</td>
<td>4.6 (0.09)</td>
<td>3, 7, 4</td>
<td>(4.4, 4.8)</td>
<td>75</td>
<td>2.4 (0.13)</td>
<td>1, 5, 2</td>
<td>(2.1, 2.7)</td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CGI-ADHD-S = Clinical Global Impressions-Attention-Deficit/Hyperactivity Disorder-Severity scale; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

1 p-value using a Wilcoxon signed rank test comparing the mean change in CGI-ADHD-S score to zero for patients completing Visit 9 or later.

2 p-value comparing the correlation between change in ADHDRS-IV-Parent:Inv and change in CGI-ADHD-S score to zero for patients completing Visit 9 or later.
Table 13. Change in CGI-ADHD-S and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 12 (1 Year)

<table>
<thead>
<tr>
<th></th>
<th>Baseline Score</th>
<th></th>
<th>Endpoint Score</th>
<th></th>
<th>Change from Baseline to Endpoint</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>95% CI</th>
<th>p-value²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
<td></td>
</tr>
<tr>
<td>CGI-ADHD-S</td>
<td>66</td>
<td>4.6 (0.10)</td>
<td>3, 7, 4 (4.4, 4.8)</td>
<td>66</td>
<td>2.3 (0.13)</td>
<td>1, 4, 2 (2.0, 2.5)</td>
<td>-2.3 (0.16)</td>
<td>-5, 0, -2 (2.6, -2.0)</td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent: Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CGI-ADHD-S = Clinical Global Impressions-Attention-Deficit/Hyperactivity Disorder-Severity scale; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean.

¹ p-value using a Wilcoxon signed rank test comparing the mean change in CGI-ADHD-S score to zero for patients completing Visit 12.

² p-value comparing the correlation between change in ADHDRS-IV-Parent:Inv and change in CGI-ADHD-S score to zero for patients completing Visit 12.
Table 14. Change in WFIRS-P Total and Subscale Scores and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 9 (6 Months) or Later

<table>
<thead>
<tr>
<th></th>
<th>Baseline Score</th>
<th></th>
<th></th>
<th>Endpoint Score</th>
<th></th>
<th>Change from Baseline to Endpoint</th>
<th>p-value1</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>95% CI</th>
<th>p-value2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
</tr>
<tr>
<td>Total</td>
<td>72</td>
<td>0.996 (0.052)</td>
<td>0.3, 2.4, 1.0</td>
<td>72</td>
<td>0.586 (0.045)</td>
<td>0.0, 1.7, 0.5</td>
<td>0.496, 0.677</td>
<td>0.410 (0.053)</td>
<td>-1.6, -0.4</td>
<td>-0.515, -0.304</td>
</tr>
<tr>
<td>Things at home</td>
<td>72</td>
<td>1.104 (0.070)</td>
<td>0.2, 2.7, 1.0</td>
<td>72</td>
<td>0.763 (0.078)</td>
<td>0.0, 2.7, 0.7</td>
<td>0.607, 0.919</td>
<td>-0.340 (0.079)</td>
<td>-1.8, -0.3</td>
<td>-0.497, -0.184</td>
</tr>
<tr>
<td>Self-concept</td>
<td>72</td>
<td>1.171 (0.097)</td>
<td>0.0, 3.0, 1.0</td>
<td>72</td>
<td>0.856 (0.092)</td>
<td>0.0, 3.0, 0.7</td>
<td>0.674, 1.039</td>
<td>-0.315 (0.105)</td>
<td>-3.0, 0.3</td>
<td>-0.525, -0.105</td>
</tr>
<tr>
<td>Things at school</td>
<td>72</td>
<td>1.380 (0.076)</td>
<td>0.2, 2.9, 1.3</td>
<td>72</td>
<td>0.673 (0.059)</td>
<td>0.0, 2.4, 0.6</td>
<td>0.554, 0.791</td>
<td>-0.708 (0.089)</td>
<td>-2.3, 1.1</td>
<td>-0.885, -0.330</td>
</tr>
<tr>
<td>Social activities</td>
<td>72</td>
<td>1.118 (0.087)</td>
<td>0.0, 3.0, 1.0</td>
<td>72</td>
<td>0.589 (0.075)</td>
<td>0.0, 2.3, 0.4</td>
<td>0.441, 0.738</td>
<td>-0.529 (0.082)</td>
<td>-2.3, 1.1</td>
<td>-0.692, -0.365</td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>72</td>
<td>0.905 (0.059)</td>
<td>0.0, 2.3,</td>
<td>72</td>
<td>0.577 (0.048)</td>
<td>0.0, 1.8,</td>
<td>0.441,</td>
<td>0.411,</td>
<td>&lt;.0001</td>
<td>0.229 (0.002, 0.457)</td>
</tr>
<tr>
<td>Risky activities</td>
<td>72</td>
<td>0.437 (0.048)</td>
<td>0.0, 1.7, 0.4</td>
<td>72</td>
<td>0.260 (0.029)</td>
<td>0.0, 0.9, 0.2</td>
<td>0.202, 0.318</td>
<td>-0.177 (0.040)</td>
<td>-1.2, 0.7</td>
<td>-0.258, -0.097</td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean; WFIRS-P = Weiss Functional Impairment Rating Scale-Parent Report.

1 p-value using a paired t-test comparing the mean change in total and subscale scores of the WFIRS-P to zero for patients completing Visit 9 or later.

2 p-value comparing the correlation between change in ADHDRS-IV-Parent:Inv and change in total and subscale scores of the WFIRS-P to zero for patients completing Visit 9 or later.
Table 15. Change in WFIRS-P Total and Subscale Scores and Correlation with Change in ADHDRS-IV-Parent:Inv for Patients who Completed Visit 12 (1 Year)

<table>
<thead>
<tr>
<th></th>
<th>Baseline Score</th>
<th>Endpoint Score</th>
<th>Change from Baseline to Endpoint</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Correlation with Change in ADHDRS-IV-Parent:Inv</th>
<th>95% CI</th>
<th>p-value&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N  Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
<td>N  Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
<td>N  Mean (SD)</td>
</tr>
<tr>
<td>Total</td>
<td>65 0.990 (0.057) 0.3, 2.4, 0.9 (0.876, 1.104)</td>
<td>65 0.568 (0.048) 0.0, 1.7, 0.5 (0.471, 0.664)</td>
<td>65 -0.422 (0.057) -1.6, 0.9, -0.4 (-0.537, -0.308)</td>
<td>&lt;.0001 0.520 (0.332, 0.707)</td>
<td>&lt;.0001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Things at home</td>
<td>65 1.091 (0.071) 0.2, 2.7, 1.0 (0.950, 1.232)</td>
<td>65 0.743 (0.081) 0.0, 2.7, 0.6 (0.581, 0.904)</td>
<td>65 -0.349 (0.063) -1.8, 1.6, -0.3 (-0.515, -0.183)</td>
<td>&lt;.0001 0.394 (0.167, 0.621)</td>
<td>0.0012</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-concept</td>
<td>65 1.267 (0.105) 0.0, 3.0, 1.0 (1.057, 1.476)</td>
<td>65 0.836 (0.097) 0.0, 3.0, 0.5 (0.642, 1.030)</td>
<td>65 -0.431 (0.078) -3.0, 2.7, -0.8 (-0.667, -0.194)</td>
<td>&lt;.0001 0.258 (0.020, 0.496)</td>
<td>0.0382</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Things at school</td>
<td>65 1.380 (0.085) 0.0, 2.9, 1.3 (1.210, 1.551)</td>
<td>65 0.644 (0.064) 0.0, 2.4, 0.5 (0.517, 0.771)</td>
<td>65 -0.737 (0.092) -2.3, 1.1, -0.7 (-0.920, -0.553)</td>
<td>&lt;.0001 0.392 (0.170, 0.614)</td>
<td>0.0012</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social activities</td>
<td>65 1.081 (0.093) 0.0, 3.0, 1.0 (0.895, 1.267)</td>
<td>65 0.503 (0.075) 0.0, 2.3, 0.3 (0.354, 0.652)</td>
<td>65 -0.578 (0.082) -2.3, 1.1, -0.7 (-0.741, -0.415)</td>
<td>&lt;.0001 0.454 (0.243, 0.664)</td>
<td>0.0001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>65 0.923 (0.067) 0.0, 2.4, 0.9 (0.788, 1.057)</td>
<td>65 0.615 (0.052) 0.0, 1.8, 0.5 (0.511, 0.718)</td>
<td>65 -0.308 (0.067) -1.5, 1.0, -0.3 (-0.442, -0.173)</td>
<td>&lt;.0001 0.347 (0.115, 0.579)</td>
<td>0.0044</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risky activities</td>
<td>65 0.412 (0.053) 0.0, 1.7, 0.3 (0.305, 0.518)</td>
<td>65 0.254 (0.031) 0.0, 0.9, 0.2 (0.191, 0.316)</td>
<td>65 -0.158 (0.046) -1.2, 0.7, -0.1 (-0.250, -0.066)</td>
<td>0.0010 0.376 (0.192, 0.561)</td>
<td>0.0020</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: ADHDRS-IV-Parent:Inv = Attention-Deficit/Hyperactivity Disorder Rating Scale-IV-Parent Version: Investigator Administered and Scored; CI = confidence interval; Min = minimum; Max = maximum; N = number of patients; SD = standard deviation of mean; WFIRS-P = Weiss Functional Impairment Rating Scale-Parent Report.

1 p-value using a paired t-test comparing the mean change in total and subscale scores of the WFIRS-P to zero for patients completing Visit 12.

2 p-value comparing the correlation between change in ADHDRS-IV-Parent:Inv and change in total and subscale scores of the WFIRS-P to zero for patients completing Visit 12.
Safety

All enrolled patients (N=105) received at least one dose of study drug. No deaths occurred during this study. One serious adverse events was reported, suicidal ideation, which occurred at Month 6 and which the investigator believed was possibly related to study drug. This event led to study discontinuation. Table 16 summarizes the treatment-emergent adverse events with ≥5% incidence rate. Table 17 summarizes the change from baseline to endpoint in vital signs, height, and weight.

Table 16. Treatment-Emergent Adverse Events with ≥5% Incidence Rate

<table>
<thead>
<tr>
<th>Preferred Term [n (%)]</th>
<th>N=105</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients reporting at least one TEAE</td>
<td>99 (94.3)</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>46 (43.8)</td>
</tr>
<tr>
<td>Headache</td>
<td>41 (39.0)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>40 (38.1)</td>
</tr>
<tr>
<td>Nausea</td>
<td>28 (26.7)</td>
</tr>
<tr>
<td>Abdominal pain upper</td>
<td>26 (24.8)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>26 (24.8)</td>
</tr>
<tr>
<td>Somnolence</td>
<td>21 (20.0)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>20 (19.0)</td>
</tr>
<tr>
<td>Cough</td>
<td>17 (16.2)</td>
</tr>
<tr>
<td>Influenza</td>
<td>17 (16.2)</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>13 (12.4)</td>
</tr>
<tr>
<td>Irritability</td>
<td>12 (11.4)</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>12 (11.4)</td>
</tr>
<tr>
<td>Pharyngolaryngeal pain</td>
<td>11 (10.5)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>10 (9.5)</td>
</tr>
<tr>
<td>Rash</td>
<td>9 (8.6)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>9 (8.6)</td>
</tr>
<tr>
<td>Affect lability</td>
<td>7 (6.7)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>7 (6.7)</td>
</tr>
<tr>
<td>Anorexia</td>
<td>6 (5.7)</td>
</tr>
<tr>
<td>Pharyngitis streptococcal</td>
<td>6 (5.7)</td>
</tr>
</tbody>
</table>

Abbreviations: n = number of patients; N = total number of patients; TEAE = treatment-emergent adverse event.
# Table 17. Mean Change in Vital Signs from Baseline to Endpoint

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Endpoint</th>
<th>Change</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>Min, Max, Median</td>
<td>95% CI</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>105</td>
<td>66.4 (0.78)</td>
<td>37, 83, 66</td>
<td>(64.9, 68.0)</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>105</td>
<td>102.1 (0.91)</td>
<td>81, 121, 101</td>
<td>(100.3, 103.9)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>102</td>
<td>137.0 (0.70)</td>
<td>119, 152, 137</td>
<td>(135.6, 138.4)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>105</td>
<td>35.5 (0.78)</td>
<td>24, 65, 35</td>
<td>(33.9, 37.0)</td>
</tr>
</tbody>
</table>

Abbreviations: BP = blood pressure; CI = confidence interval; Min = minimum; Max = maximum; N = total number of patients; SD = standard deviation of mean.

* p-value using a paired t-test or Wilcoxon signed rank test comparing the mean change to zero.
References:


