



Consumer Press Statement

STRICTLY EMBARGOED UNTIL 00:01 GMT TUESDAY 11th July 2006

Quality of life of children with ADHD within the lowest 5% of the population

Experts call for increased consideration of quality of life in treatment decision

10th July 2006, Chicago, USA: The results of a new UK study¹ released today showed that children with ADHD (attention-deficit/hyperactivity disorder) have dramatically poor quality of life compared to their peers*. According to the findings, the average quality of life 'scores' of children with ADHD were within the lowest 5% of the population - their condition was shown to have a significantly negative impact on self-esteem and achievement at school, as well as on ability to make friends and interact with others. However, the pioneering study which was the first to ask children with ADHD and their parents about how the condition affects their personal wellbeing, offers hope for those coping with the condition by showing that ADHD treatments can improve not only children's symptoms, but can also significantly improve their quality of life.

Dr Val Harpin, a Paediatrician at Sheffield's Children's Hospital who was involved in the study commented: "ADHD often has a significant effect on the quality of life of a child and their family. This means that a child may have difficulties in school, find it hard to make friends and enjoy times with their family, and self-esteem can be worryingly low. We now have sound evidence that treatment can improve quality of life for child and family substantially."

Tending to focus on the effectiveness of treatment, quality of life is not often specifically taken into consideration when thinking about the best way to treat and manage a child's ADHD.² However, ADHD experts involved in the trial are now encouraging both doctors and parents to seek the best available treatments and therapies to help minimise the negative impact that ADHD can have upon their child's life.



The “SUNBEAM” study represents a major step forward in researching ADHD and a novel approach to evaluating the effectiveness of treatments. During the 10-week trial period, there was a greater increase in the quality of life of children on the non-stimulant medication atomoxetine (Strattera®) compared with standard current therapy as measured by the Parent Report Form of the Child Health and Illness Profile-Child Edition (CHIP-CE). The average scores at week 10 were 38.4 compared to 30.8 respectively.**

According to Charlotte Williams, whose 16 year old son was diagnosed with ADHD 6 years ago, an effective treatment strategy can turn a child’s life around: “It used to be a real struggle – Joe had a hard time keeping friends and interacting with the adults in his life. As a family we avoided going out, visiting friends and family, or having people round - it was just too difficult. Medication really was a last resort and after considering all the options Joe started treatment 5 years ago. Life improved so much after that for both Joe and the whole family. We were able to start doing normal family activities and Joe’s self-confidence skyrocketed. He has since grown into a happy, fun-loving teenage boy.”

It has long been understood that children with severe ADHD can experience emotional and social problems as a result of and therefore accentuating their condition, including low self-esteem and under-achievement at school.³ The poor quality of life of children with ADHD can have profound effects in later life. Research shows that children with ADHD are more likely to suffer from learning difficulties,⁴ and teenagers have an increased probability of using drugs, having anti-social personalities, lower-status jobs and failing at school than other children.⁵ In fact, research has suggested that children with ADHD have as comparably poor a quality of life as those with cerebral palsy or receiving chemotherapy/radiation for the treatment of newly diagnosed cancer.⁶

These results come at a time when the European Commission is developing legislation to encourage research into medicines developed specifically for children. The SUNBEAM trial continues for a further six months, providing valuable ‘real-life’ and clinically-relevant information on the use of ADHD medications in children.



* The rating scale to measure quality of life was developed in the US therefore norms are calculated from US children (scores are standardised to an average score of 50)

** Standard Current Therapy (SCT) was defined as the most optimal treatment for the patient in the investigators clinical judgement. This could include behavioural counselling and any combination of pharmacotherapy (apart from atomoxetine). Treatment in this arm could be changed or supplemented at any time during the 10 week period. Formal structured psychotherapy was excluded because it would interfere with the visit schedule and also because such services are disparate across the UK. Most children (96-97% over the 10 weeks) who were on current standard therapy were taking methylphenidate (short- or long-acting, alone or in combination with another drug).

- ends -

The SUNBEAM trial is funded by Lilly.


Notes to Editors:

About ADHD

- ADHD affects 5% or 366,000 children in the UK and the typical symptoms include inattention, hyperactivity and impulsiveness³ which are not normal for a child of that age and development level
- ADHD is thought to be caused by an imbalance of the chemicals used to signal between nerve cells in the brain

ADHD and quality of life

- Children with ADHD often feel badly about themselves - they might think they are stupid, naughty, bad or a failure
- Hyperactive and disruptive behaviour are key factors of ADHD which people often misunderstand. This can lead to problems in school and at home, with difficulties making and keeping friends

- 
- ADHD is known to have a significant impact on the family as well as achievement at school³

About ADHD treatment


- The National Institute for Health and Clinical Excellence (NICE), the organisation providing guidance on health and treatments, recommends that the preferences of the child and his/her parent or guardian is one of the key considerations when choosing a treatment for ADHD³
- Methylphenidate, atomoxetine or dexamfetamine are all recommended within their licensed indications as options for the management of ADHD in children and adolescents³
- The SUNBEAM study highlights the broader effects of different treatments, and could help parents as they discuss the treatment options with their child's doctor

About the SUNBEAM research

- 201 children with ADHD were treated with either atomoxetine or 'standard current therapy' (the doctor's choice of the best treatment for the child, excluding atomoxetine)
- Children and parents were asked a series of quality of life questions at the start of treatment and at intervals during the 10-week research period. Three quality of life scales were used, including the Child Health and Illness Profile
- The child's quality of life improved significantly over the 10-weeks with greatest improvements for the children taking atomoxetine. In this study atomoxetine was also more effective at reducing the core ADHD symptoms
- The SUNBEAM trial was funded by Lilly

About Lilly

- Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Lilly provides answers – through medicines and information – for some of the world's most urgent medical needs.



Additional information about Lilly is available at www.lilly.co.uk. Data from Lilly clinical trials is available at www.lillytrials.com.

- Any adverse events of Lilly medicines should be reported to Eli Lilly and Company Limited: Tel no. 0870 240 1125, or reported through www.yellowcard.gov.uk

Spokespeople available for interview include:

- Charlotte Williams, parent of a child with ADHD
- Dr Val Harpin, Paediatrician from Sheffield's Children's Hospital
- Andrea Bilbow, founder and Chief Executive of ADHD charity ADDISS

For further information and interviews, please contact Virgo Health PR:

Andrea Petruzella 020 8939 2453 andrea.petruzella@virgohealthpr.com

Polly Lutter 020 8939 2471 polly.lutter@virgohealthpr.com

References

1. Prasad, S et al. SUNBEAM: A Randomised, controlled, open-label study of the broader efficacy of atomoxetine compared with standard current therapy in a group of UK children and adolescents with attention-deficit/hyperactivity disorder. Poster presented at CINP (Collegium Internationale Neuro-Psychopharmacologium), Chicago, July 2006.
2. Prasad S & Poole L. Assessing quality of life in children and adolescents with ADHD: SUNBEAM, an open comparative study of atomoxetine and standard therapy. *Patient Reported Outcomes Newsletter* 2006; **36**: 16-19
3. National Institute for Health and Clinical Excellence (NICE). Methylphenidate, atomoxetine and dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents. Technology Appraisal 98. March 2006.
4. Pastor PN & Reuben CA. Attention deficit disorder and learning disability: United States, 1997-1998. *Vital and Health Statistics* . **10**; 2002; 206: 1-12
5. Elia J, Ambrosini PJ & Rapoport JL. Treatment of attention-deficit-hyperactivity disorder. *New England Journal of Medicine* 1999; **11**: 340(10): 780-88



6. Varni, J and Burwinkle, T. The PedsQL™ as a patient-reported outcome in children and adolescents with Attention-Deficit/Hyperactivity Disorder: a population-based study. *Health and Quality of Life Outcomes* 2006; 4: 26

AMX 754 Prepared June 2006