

## Targacept Announces Positive Top-Line Results from Phase II Study of AZD3480 in Adult ADHD

Winston-Salem, NC May 11, 2009

Targacept, Inc. (NASDAQ: TRGT) today announced preliminary results showing that AZD3480 (TC-1734) met the primary outcome measure in a Phase II clinical study in adults with attention deficit/hyperactivity disorder (ADHD).

In the study, adult subjects received in random order daily doses of 5mg of AZD3480, 50mg of AZD3480 and placebo, each for two weeks with the dosing periods separated by a three-week washout period. At 50mg AZD3480, subjects showed statistically significant ( $p < .01$ ) improvement in symptoms of ADHD as measured by the study's primary outcome measure, total symptom score on the Conners Adult ADHD Rating Scale – Investigator Rating (CAARS-INV). Data from the study on CAARS-INV are shown in the table below.

	Completed Subjects	Pre-Treatment Mean (Standard Deviation)	Post-Treatment Mean (Standard Deviation)	Mean Change (Standard Deviation)
placebo	24	37.7 (5.45)	36.9 (5.20)	0.8 (5.33)
5mg AZD3480	23	39.6 (5.36)	34.9 (5.24)	4.7 (5.30)
50mg AZD3480	24	40.3 (5.40)	33.1 (5.34)	7.2 (5.37)

Statistically significant results were also achieved at 50mg AZD3480 on a number of secondary outcome measures in the study, including Stop Signal Reaction Time, a computerized assessment of behavioral inhibition, which is a core cognitive deficit of ADHD.

AZD3480 was well tolerated in the study, and there were no serious adverse events.

"In this study AZD3480 positively affected the core symptoms of adult ADHD patients. The results showed a consistent effect between improvements in clinical symptoms and a core cognitive deficit. Additionally, we saw improvement after just one week of treatment with the 50mg dose of AZD3480 and then continued improvement at the end of the second week," commented Paul A. Newhouse, M.D., Professor of Psychiatry and Director, Clinical Neuroscience Research Unit and Brain Imaging Program, [University of Vermont College of Medicine](#), and the principal investigator for the study.

"These results further our belief in AZD3480's potential to benefit patients and reinforce our longstanding commitment to the neuronal nicotinic receptor mechanism. AZD3480 has now been studied in over 1,350 subjects providing us and AstraZeneca with substantial data," said J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept.

“We are encouraged by the preliminary results of the study presented to us. There is a compelling need to develop novel, well-tolerated, non-stimulant medicines to meet the needs of patients with ADHD,” said Bob Holland, Vice President Neuroscience and Head of the Neuroscience Therapy Area, AstraZeneca. “We look forward to completing a full analysis of the data set and then making our decisions around the future development of this compound.”

## **Next Steps**

Analyses of the full dataset from the study remain ongoing. AstraZeneca and Targacept plan to present and publish more detailed results from the study at a future scientific meeting.

AstraZeneca is expected to determine whether to conduct further development of AZD3480 in ADHD and/or Alzheimer's disease in the second quarter of 2009.

## **Study Design**

- Double blind, placebo controlled, crossover study conducted at Fletcher Allen Health Care, an affiliate of the University of Vermont College of Medicine.
- Subjects were between the ages of 18 and 65, male and female, non-smokers, diagnosed with ADHD based on DSM-IV criteria and had a baseline score of at least 4 on the Clinical Global Impression – Severity scale.
- Efficacy dataset included 24 completed subjects.
- Each subject received in random order 5mg of AZD3480, 50mg of AZD3480 and placebo, in each case daily for two weeks, with the dosing periods separated by a three-week washout period designed to minimize carryover effects. As a result, each subject served as his or her own control.
- The primary outcome measure was the change in total symptom score on the Conners Adult ADHD Rating Scale – Investigator Rating (CAARS-INV) following two weeks dosing with AZD3480 as compared to two weeks dosing with placebo.

## ***Conference Call***

As previously announced, Targacept will be hosting a conference call and webcast today, May 11, 2009, at 9:00 a.m. Eastern Daylight Time, to discuss its first quarter 2009 financial results, provide an update on the company's product development programs and business activities and discuss expectations for the future. The conference call may be accessed by dialing 800-291-9234 for domestic participants and 617-614-3923 for international callers (reference passcode 29368344). A replay of the conference call may be accessed beginning at approximately 12:00 p.m. on May 11, 2009 and continuing at least through May 25, 2009 by dialing 888-286-8010 for domestic callers and 617-801-6888 for international callers (reference passcode 96577819).

A live audio webcast of the conference call will be accessible from the Investor Relations page of Targacept's website, [www.targacept.com](http://www.targacept.com). To ensure a timely connection to the webcast, it is recommended that users register at least 15 minutes prior to the scheduled start time. An archived version of the webcast will also be available on the Investor Calendar section of the Investor Relations page of Targacept's website for at least two weeks following the call.

## **About Adult ADHD**

ADHD is a condition that develops during childhood and, if not adequately treated, can have long-term adverse effects into adolescence and adulthood. The principal characteristics of ADHD are inattention, hyperactivity and impulsivity. For an adult to be diagnosed with ADHD, the ADHD symptoms must have begun during childhood and continued throughout adulthood. The market research firm Business Insights estimated that, in 2008, there were approximately 25 million adults with ADHD in the world's seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan).

## **About Targacept**

Targacept is a clinical-stage biopharmaceutical company that discovers and develops NNR Therapeutics (TM), a new class of drugs primarily for the treatment of central nervous system diseases and disorders. Targacept's product candidates selectively modulate neuronal nicotinic receptors that serve as key regulators of the nervous system to promote therapeutic effects and limit adverse side effects. Targacept has clinical-stage product candidates in development for major depressive disorder, Alzheimer's disease, attention deficit/hyperactivity disorder, cognitive dysfunction in schizophrenia and resistant hypertension, as well as multiple preclinical programs. Targacept also has a cognition-focused collaboration with AstraZeneca and a strategic alliance with GlaxoSmithKline. Targacept's news releases are available on its website at [www.targacept.com](http://www.targacept.com).

## **Forward-Looking Statements**

Statements in this press release that are not purely historical in nature constitute "forward-looking statements" made under the provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, statements regarding the timing for a decision by AstraZeneca as to whether to conduct further development of AZD3480 in Alzheimer's disease or ADHD, the presentation of full results from the Phase 2 trial of AZD3480 in adults with ADHD, the potential benefits of AZD3480 or Targacept's plans, expectations, future operations, financial position, revenues, costs or expenses. Actual results may differ materially from those expressed or implied by forward-looking statements as a result of various important factors, including, without limitation, risks and uncertainties relating to the significant control that AstraZeneca has over the development of AZD3480, including as to whether to conduct any further development of AZD3480 in Alzheimer's disease or ADHD. These and other risks and uncertainties are described in greater detail under the heading "Risk Factors" in Targacept's most recent Annual Report on Form 10-K and in other filings that it makes with the Securities and Exchange Commission. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. Targacept cautions you not to place undue reliance on any forward-looking statement.

In addition, any forward-looking statements in this release represent Targacept's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Targacept anticipates that subsequent events and developments may cause its views to change. Although Targacept may elect to update these forward-looking statements publicly at some point in the future, it specifically disclaims any obligation to do so, except as required by applicable law.

*NNR Therapeutics (TM) is a trademark of Targacept, Inc. Any other service marks, trademarks and trade names appearing in this press release are the properties of their respective owners.*

## **Targacept Contacts:**

Alan Musso, VP and CFO

Targacept, Inc.

Tel: (336) 480-2186

Email: [alan.musso@targacept.com](mailto:alan.musso@targacept.com)

Michelle Linn

Linnden Communications

Tel: (508) 362-3087

Email: [linnmich@comcast.net](mailto:linnmich@comcast.net)