Axsome Therapeutics Provides Update on Continued Progress at Annual Stockholders' Meeting

June 7, 2019

Placebo-controlled Phase 3 trial of AXS-05 in MDD on track to start in 2Q 2019

Topline results from both STRIDE-1 Phase 3 trial in TRD and planned placebo-controlled Phase 3 trial in MDD for AXS-05 still anticipated in 2H 2019

Phase 3 MOMENTUM trial of AXS-07 in migraine on track for readout of topline results in 2H 2019

Phase 2 CONCERT trial results of AXS-12 in narcolepsy now anticipated in 2H 2019

Current cash sufficient to fund anticipated operations beyond all clinical trial readouts

NEW YORK, June 07, 2019 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, is providing the following update on the Company's continued progress at its Annual Meeting of Stockholders being held today:

AXS-05

AXS-05 (dextromethorphan/bupropion) is Axsome's novel, oral, investigational NMDA receptor antagonist with multimodal activity being developed for the following indications: treatment resistant depression (TRD), major depressive disorder (MDD), Alzheimer's disease (AD) agitation, and smoking cessation. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation for the treatment of MDD and Fast Track designations for the treatment of TRD and for the treatment of AD agitation.

Depression

- Axsome continues to expect topline results from the ongoing Phase 3 STRIDE-1 trial of AXS-05 in TRD in the second half of 2019.
- Axsome is on track to initiate its planned placebo-controlled Phase 3 trial of AXS-05 in MDD this quarter with topline results anticipated in the second half of 2019.
- An NDA filing for AXS-05 in the treatment of MDD is targeted for 2020.

Alzheimer's Disease Agitation

- Axsome remains on track to report topline results from the ongoing Phase 2/3 ADVANCE-1 trial of AXS-05 in agitation associated with Alzheimer's disease in the first half of 2020.

AXS-07

AXS-07 (MoSEIC™ meloxicam/rizatriptan) is Axsome's novel, oral, investigational medicine with distinct dual mechanisms of action being developed for the acute treatment of migraine.

- Based on the continued faster-than-expected enrollment in the MOMENTUM Phase 3 trial of AXS-07 in the acute treatment of migraine, Axsome continues to anticipate topline results from this trial in the second half of 2019. MOMENTUM is being conducted pursuant to an FDA Special Protocol Assessment (SPA).

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, potent and highly selective norepinephrine reuptake inhibitor being developed for the treatment of narcolepsy. AXS-12 has been granted Orphan Drug Designation by the FDA for the treatment of narcolepsy.

- Based on current enrollment trends, Axsome now anticipates topline results from the CONCERT Phase 2 trial of AXS-12 in narcolepsy in the second half of 2019 versus previous guidance of the second quarter of 2019.

Financial Update

- Axsome believes that its current cash will be sufficient to fund the Company's anticipated operations, based on its current operating plans, into at least the first quarter of 2021, or approximately 1 year beyond the readout of all of the above ongoing and planned clinical trials.
- Axsome currently does not anticipate future equity financings prior to the readout from its Phase 3 trials.

Anticipated Clinical Trial Readouts

- Phase 3 STRIDE-1 trial of AXS-05 in TRD, topline data (2H 2019)
- Phase 3 placebo-controlled trial of AXS-05 in MDD, topline data (2H 2019)
- Phase 3 trial of AXS-07 in the acute treatment of migraine, topline data (2H 2019)
- Phase 2 trial of AXS-12 in narcolepsy, topline data (2H 2019)
- Phase 2/3 ADVANCE-1 trial of AXS-05 in AD agitation, topline data (1H 2020)

About AXS-05

AXS-05 is a novel, oral, patent-protected, investigational NMDA receptor antagonist with multimodal activity under development for the treatment of major depressive disorder and other central nervous system (CNS) disorders. AXS-05 consists of a proprietary formulation and doses of dextromethorphan and bupropion and utilizes Axsome's metabolic inhibition technology. The dextromethorphan component of AXS-05 is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist, also known as a glutamate receptor modulator, which is a novel mechanism of action, meaning it works differently than currently available therapies for depression. The dextromethorphan component of AXS-05 is also a sigma-1 receptor agonist, nicotinic acetylcholine receptor antagonist, and inhibitor of the serotonin and norepinephrine transporters. The bupropion component of AXS-05 serves to increase the bioavailability of dextromethorphan, and is a norepinephrine and dopamine reuptake inhibitor, and a nicotinic acetylcholine receptor antagonist. AXS-05 is covered by more than 30 issued U.S. and international patents which provide protection out to 2034. AXS-05 is not approved by the FDA.

About AXS-07

AXS-07 is a novel, oral, investigational medicine with distinct dual mechanisms of action under development for the acute treatment of migraine. AXS-07 consists of MoSEIC™ meloxicam and rizatriptan. Meloxicam is a new molecular entity for migraine enabled by Axsome's MoSEIC (Molecular Solubility Enhanced Inclusion Complex) technology, which results in rapid absorption of meloxicam while maintaining a long plasma half-life. Meloxicam is a COX-2 preferential non-steroidal anti-inflammatory drug and rizatriptan is a 5-HT1B/D agonist. AXS-07 is designed to provide rapid, enhanced and consistent relief of migraine, with reduced symptom recurrence. AXS-07 is not approved by the FDA.

About AXS-12

AXS-12 (reboxetine) is a novel, oral, investigational medicine in development for the treatment of the symptoms of narcolepsy. AXS-12 is a highly selective and potent norepinephrine reuptake inhibitor. AXS-12 is an investigational drug product not approved by the FDA.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. Axsome's core CNS product candidate portfolio includes four clinical-stage candidates, AXS-05, AXS-07, AXS-09, and AXS-12. AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), and a Phase 2/3 trial in agitation associated with Alzheimer's disease (AD). AXS-05 is also being developed for major depressive disorder (MDD) and smoking cessation treatment. AXS-07 is currently in a Phase 3 trial for the acute treatment of migraine. AXS-12 is currently in a Phase 2 trial in narcolepsy. The Axsome Pain and Primary Care business unit (Axsome PPC) houses Axsome's pain and primary care assets, including AXS-02 and AXS-06, and intellectual property which covers these and related product candidates and molecules being developed by Axsome and others. AXS-02 is being developed for osteoporosis, the pain of knee osteoarthritis, and chronic low back pain. AXS-06 is being developed for osteoarthritis and rheumatoid arthritis. AXS-02, AXS-05, AXS-06, AXS-07, AXS-09, and AXS-12 are investigational drug products not approved by the FDA. For more information, please visit the Company's website at axsome.com. The Company may occasionally disseminate material, nonpublic information on the company website.

Forward Looking Statements

Certain matters discussed in this press release are "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company's statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials, futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our ongoing clinical trials, and the number or type of studies or nature of results necessary to support the filing of a new drug application ("NDA") for any of our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates (including, but not limited to, FDA's agreement with the Company's plan to discontinue the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee's recommendations); the potential for the ASCEND clinical trial to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients; the Company's ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's license agreements; the acceptance by the market of the Company's product candidates, if approved; the Company's anticipated capital requirements; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

Axsome Contact:
Mark Jacobson

Senior Vice President, Operations
Axsome Therapeutics, Inc.
200 Broadway, 3rd Floor
New York, NY 10038
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

Source: Axsome Therapeutics, Inc.