Axsome Therapeutics to Host R&D Day with Key Opinion Leaders Focused on AXS-05 and Unmet Needs in Depression, Alzheimer's Disease Agitation, and Nicotine Dependence

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NEW YORK, March 27, 2018 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ:AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced that it will host a research and development (R&D) day with key opinion leaders (KOLs), highlighting the company's CNS product candidate AXS-05, and unmet needs in depression, agitation associated with Alzheimer's disease, and nicotine dependence, on Tuesday, April 24, 2018 in New York City.

The event will feature presentations by Maurizio Fava, MD (Massachusetts General Hospital), Marc Agronin, MD (University of Miami), and James Davis, MD (Duke University), who will discuss the current treatment landscape and unmet medical needs for patients with treatment resistant depression, agitation associated with Alzheimer's disease, and nicotine dependence, respectively; and a presentation by Stephen Stahl, MD, PhD, DSc (University of California, San Diego) who will discuss the unique pharmacology of AXS-05 (bupropion and dextromethorphan) and its relevance to these conditions. The presenters will be available to answer questions following their presentations.

The Axsome executive management team will also provide an update on the ongoing clinical development of AXS-05 as well as on the rest of the Company's CNS pipeline.

KOL Presenters:

- **Stephen M. Stahl, MD, PhD, DSc (Hon).** Adjunct Professor of Psychiatry, University of California San Diego; Honorary Visiting Senior Fellow, University of Cambridge, UK; Chairman, Neuroscience Education Institute; Chairman, Arbor Scientia Group; Editor-in Chief, CNS Spectrums; and Director of Psychopharmacology Services and Senior Academic Advisor, California Department of State Hospitals

- **Maurizio Fava, MD.** Director, Division of Clinical Research of the Massachusetts General Hospital (MGH) Research Institute; Executive Vice Chair of the Department of Psychiatry and Executive Director of the Clinical Trials Network and Institute (MGH); and Associate Dean for Clinical and Translational Research and the Slater Family Professor of Psychiatry at Harvard Medical School

- **Marc Agronin, MD.** Vice President of Behavioral Health and Clinical Research at Miami Jewish Health; and Affiliate Associate Professor of Psychiatry and Neurology at University of Miami Miller School of Medicine

- **James Davis, MD.** Medical Director of the Duke Center for Smoking Cessation; Director of the Duke Smoking Cessation Program; Co-Director of the Duke-UNC Tobacco Treatment Specialist Training Program; and Associate Professor of Medicine, Duke University School of Medicine

AXS-05 is a novel glutamatergic and monaminergic product candidate under development for the treatment of CNS disorders. It is currently being evaluated in the STRIDE-1 Phase 3 trial in treatment resistant depression and the ADVANCE-1 Phase 2/3 trial in agitation associated with Alzheimer's disease. A Phase 2 trial of AXS-05 in smoking cessation is planned. AXS-05 has been granted U.S. Food and Drug Administration Fast Track designations for treatment resistant depression and for agitation associated with Alzheimer's disease.

This event is intended for institutional investors, sell-side analysts, and business development professionals only. Please RSVP in advance if you plan to attend, as space is limited. To reserve a seat email Kimberly Kenney at kkenney@axsome.com.

A live and archived webcast of the event, with slides, can be accessed on the investor page of Axsome's website at www.axsome.com.

KOL Credentials

- **Stephen M. Stahl, MD, PhD, DSc (Hon)**

  Dr. Stahl has held faculty positions at Stanford University, the University of California at Los Angeles, the Institute of Psychiatry London, the Institute of Neurology London, and, currently, as professor at the University of California at San Diego and as Honorary Fellow in Psychiatry at the University of Cambridge. Dr. Stahl serves as editor-in-chief of CNS

Spectrums journal.

Author of over 500 articles and chapters, and more than 1,600 scientific presentations and abstracts, Dr. Stahl is an internationally recognized clinician, researcher, and teacher in psychiatry with subspecialty expertise in psychopharmacology. Dr. Stahl has written 39 textbooks and edited 13 others, including the best-selling and award-winning textbook, Stahl's Essential Psychopharmacology, and clinical manual, Essential Psychopharmacology Prescriber's Guide. Dr. Stahl is Senior Academic Advisor and Director of Psychopharmacology for the California Department of State Hospitals (DSH) where he has a leadership role in addressing violence in the five-hospital, 6,500 patient DSH. He has been awarded the International College of Neuropsychopharmacology Lundbeck Foundation Award in Education for his contributions to postgraduate education in psychiatry and neurology. His books have won the British Medical Association's Book of the Year Award. Dr. Stahl is the recipient of numerous scientific and clinical awards and honors.

- **Maurizio Fava, MD**

  Dr. Maurizio Fava is the Director of the Clinical Research Program, Executive Vice Chair of the Department of Psychiatry, and Executive Director of the Clinical Trials Network and Institute, at Massachusetts General Hospital. Dr. Fava is also the Slater Family Professor of Psychiatry, and Associate Dean for Clinical and Translational Research, at Harvard Medical School.

  Dr. Fava is a world leader in the field of depression. He has edited eight books and authored or co-authored more than 900 original articles published in medical journals with international circulation, articles which have been cited more than 60,000 times in the literature and with an h index of over 120. Dr. Fava obtained his medical degree from the University of Padova School of Medicine and completed residency training in endocrinology at the same university. He then moved to the United States and completed residency training in psychiatry at MGH. He founded and was director of the hospital's Depression Clinical and Research Program from 1990 until 2014. In 2007, he also founded and is now the executive director of the MGH Psychiatry Clinical Trials Network and Institute, the first academic CRO specialized in the coordination of multi-center clinical trials in psychiatry. Dr. Fava's prominence in the field is reflected in his role as the co-principal investigator of STAR*D, the largest research study ever conducted in the area of depression, and of the RAPID Network, the NIMH-funded series of studies of novel, rapidly-acting antidepressant therapies. Dr. Fava has received several awards during his career and is on the editorial board of five international medical journals.

- **Marc Agronin, MD**

  Dr. Marc Agronin is the Vice President of Behavioral Health and Clinical Research at Miami Jewish Health (MJH), and Affiliate Associate Professor of Psychiatry and Neurology at University of Miami Miller School of Medicine.

  Dr. Agronin is an award-winning geriatric psychiatrist and a national expert in the field of Alzheimer's research and intervention. Dr. Agronin is the founding and current director of the Mental Health and Memory Center and Alzheimer's clinical research program at MJH, Florida's largest not-for-profit long-term care provider. The center provides evaluation and treatment of memory disorders, mood and associated behavior problems, and conducts research trials in these conditions. He is a graduate of Harvard University, summa cum laude, and the Yale School of Medicine. Dr. Agronin trained in psychiatry at Harvard Medical School and later completed a fellowship in geriatric psychiatry at the VA Medical Center in Minneapolis, MN. He has authored numerous books and scientific articles, including "Alzheimer's Disease and Other Dementias, A Practical Guide, 3rd Edition," the acclaimed "How We Age: A Doctor's Journey into the Heart of Growing Old," and its sequel "The End of Old Age: Living a Longer, More Purposeful Life". Dr. Agronin currently writes a regular blog for the Experts panel of the Wall Street Journal and lectures extensively around the country, including annual presentations at the U. S. Psychiatric Congress.

- **James Davis, MD**

  Dr. James Davis is the Medical Director of the Duke Center for Smoking Cessation, Director of the Duke Smoking Cessation Program, Co-Director of the Duke-UNC Tobacco Treatment Specialist Training Program, and Associate Professor of Medicine at Duke University School of Medicine.

  Dr. Davis is an investigator on 23 clinical trials funded through the National Institutes on Drug Abuse, National Cancer Institute, and the American Lung Association. His main area of research is development and testing of tobacco dependence treatments and is currently investigating new pharmacotherapies, adaptive medication regimens, telemedicine, and integration of therapeutic technologies. At Duke Center for Smoking Cessation, Dr. Davis works closely with Dr. Jed Rose, co-developer of the nicotine patch and other nationally acclaimed leaders in animal and neurobehavioral tobacco treatment research. Investigators in this group collectively claim over 500 tobacco treatment publications in the last decade.

Additionally, Dr. Davis oversees a network of specialized tobacco treatment clinics providing services within Duke Cancer Institute, Duke Primary Care, Duke Perioperative Medicine, Duke Infectious Disease, Duke Pulmonology, and Duke Hospitals and Hospital-Based Clinics. As co-director of the Duke-UNC Tobacco Treatment Specialist Training Program, Dr. Davis co-authors a 350-page authoritative training manual on tobacco dependence. This program provides a nationally recognized credential with regular training to medical providers across the Southeastern US. Finally, Dr. Davis was committee chair for development of National Comprehensive Cancer Network 2017 Tobacco Treatment Guideline and serves as an advisor to the North Carolina General Assembly Tobacco Treatment Taskforce and North Carolina Tobacco Prevention and Control Branch.

About AXS-05

AXS-05 is a novel, oral, investigational drug product under development for the treatment of central nervous system (CNS) disorders. AXS-05 consists of bupropion and dextromethorphan and utilizes Axsome's metabolic inhibition technology. Dextromethorphan is an NMDA receptor antagonist, sigma-1 receptor agonist, nicotinic acetylcholine receptor antagonist, and inhibitor of the serotonin and norepinephrine transporters. Bupropion serves to increase the bioavailability of dextromethorphan, and is a norepinephrine and dopamine reuptake inhibitor, and a nicotinic acetylcholine receptor antagonist. AXS-05 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 product candidate portfolio includes five clinical-stage candidates, AXS-02, AXS-05, AXS-06, AXS-07, and AXS-09. 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 smoking cessation. AXS-02 is currently in a Phase 3 trial in knee osteoarthritis (OA) associated with bone marrow lesions (BMLs) with an additional Phase 3 trial planned in chronic low back pain (CLBP) associated with Modic changes (MCs). AXS-07 is being developed for the acute treatment of migraine. AXS-06 is being developed for the treatment of osteoarthritis and rheumatoid arthritis and for the reduction of the risk of NSAID-associated gastric ulcers. AXS-02, AXS-05, AXS-06, AXS-07, and AXS-09 are investigational drug products not approved by the FDA. For more information, please visit the company website at www.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". The Company 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 the Company's ongoing clinical trials and anticipated clinical trials for its current product candidates, including statements regarding the timing of initiation, interim analyses and completion of the trials; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, its product candidates; 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; 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.

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