Akari Therapeutics Expands Clinical and Regulatory Teams with Industry Veterans

NEW YORK and LONDON, January 4, 2017 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, clinical-stage biopharmaceutical company, has expanded its clinical and regulatory teams. In December 2016, Dr. Brihad Abhyankar joined as Head of Clinical Development and Justine Lees joined as European Head of Regulatory Affairs. In January 2017, Nigel A.S. Hernandez, PhD, joined as Vice President of Worldwide Regulatory Affairs.

"We are very excited to expand our clinical and regulatory teams with these industry veterans," said Dr. Gur Roshwalb, Chief Executive Officer of Akari Therapeutics. "The clinical and regulatory experience of these new team members will help prepare us for our Phase III clinical program, which we currently expect to begin in the summer of 2017, as well as accelerate our expansion into new clinical indications,"

Brihad Abhyankar

Dr. Brihad Abhyankar MS FRCS MBA FFPM joined Akari as Head of Clinical Development. Dr. Abhyankar has 14 years of experience in the pharmaceutical industry working in clinical development and medical affairs for many mid- to large-size pharmaceutical companies. Prior to joining the pharmaceutical industry, he originally trained and worked as a surgeon. Most recently, he was Executive Director of global R&D at Takeda Pharmaceuticals and global clinical lead for an innovative monoclonal antibody developed for treatment of Crohn's disease and ulcerative colitis that has now been registered in more than 50 countries.

Justine Lees

Justine Lees joined Akari as European Head of Regulatory Affairs and has more than 25 years of biopharmaceutical experience, including 20 years in Regulatory Affairs. Ms. Lees has worked for both large and small pharmaceutical companies and for clinical research organizations at a variety of levels covering a number of different territories and her responsibilities have included global oversight of various projects both in development and in already-marketed drugs. Her experience encompasses novel chemical entities and biotechnology compounds in a variety of different therapeutic areas, including oncology, anti-infectives, CV, CNS, rare diseases, generics and biosimilars. She has extensive experience of early phase development, agency scientific advice, orphan drug designations, pediatric development plans and clinical trials. She is a member of TOPRA and an active participant of TOPRA clinical development and global development CRED courses. She is also a member of the DIA pediatric scientific interest group.

Nigel A.S. Hernandez

Nigel Hernandez, PhD, MSc, RAC joined Akari as Vice President of Worldwide Regulatory Affairs. Nigel has more than 20 years of global regulatory experience (nonclinical through commercial) in the pharmaceutical industry. He began his regulatory career at Biopure, then worked at LeukoSite (acquired by Millennium), Millennium Pharmaceuticals, GMP Regulatory, Archemix Corp, ARIAD Pharmaceuticals and Tarsa Therapeutics, where he held roles of increasing responsibility. At Actelion Pharmaceuticals, he was responsible for global regulatory leadership and strategy for Veletri (epoprostenol) and Zavesca (miglustat), including several early and late-stage developmental products in the cardiovascular,

oncology and neurology therapeutic areas. He was most recently at Esperion Therapeutics where he led the global regulatory development of bempedoic acid to lower elevated levels of low-density lipoprotein cholesterol (LDL-C).

About Akari Therapeutics Plc

Akari is a clinical-stage biopharmaceutical company focused on the development and commercialization of life-transforming treatments for a range of rare and orphan autoimmune and inflammatory diseases caused by dysregulation of complement C5 and Leukotriene B4 (LTB4), including paroxysmal nocturnal hemoglobinuria ("PNH"), atypical Hemolytic Uremic Syndrome ("aHUS"), and Guillain Barré syndrome ("GBS"). Akari's lead product candidate, Coversin™ complement inhibitor, a second-generation complement inhibitor, acts on complement component-C5, preventing the release of C5a and the formation of C5b–9 (also known as the membrane attack complex or MAC), and independently also inhibits LTB4 activity. C5 inhibition is growing in importance in a range of rare autoimmune diseases related to dysregulation of the complement component of the immune system, including PNH, aHUS, and GBS. Exploiting the power of nature, Akari is also developing other tick derived proteins and expects to bring additional compounds to clinical trials over the next several years. The pipeline is focused on developing bioengineered versions of native tick salivary proteins that act as anti-inflammatory compounds allowing the tick to remain on its host. These compounds include PGP sparing LTB4 inhibitors, classical and alternative complement inhibitors, anti-histamines, and serotonin inhibitors as examples. Akari is also developing engineered forms that allow for potential oral absorption, as, for example, a potential orally absorbed C5 inhibitor, and tissue specific proteins, as, for example, Coversin™ that acts specifically at the neuromuscular junction for diseases like myasthenia gravis.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control. Such risks and uncertainties for our company include, but are not limited to: an inability or delay in obtaining required regulatory approvals for Coversin and any other product candidates, which may result in unexpected cost expenditures; risks inherent in drug development in general; uncertainties in obtaining successful clinical results for Coversin and any other product candidates and unexpected costs that may result therefrom; failure to realize any value of Coversin and any other product candidates developed and being developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; inability to develop new product candidates and support existing product candidates; the approval by the FDA and EMA and any other similar foreign regulatory authorities of other competing or superior products brought to market; risks resulting from unforeseen side effects; risk that the market for Coversin may not be as large as expected; inability to obtain, maintain and enforce patents and other intellectual property rights or the unexpected costs associated with such enforcement or litigation; inability to obtain and maintain commercial manufacturing arrangements with third party manufacturers or establish commercial scale manufacturing capabilities; the inability to timely source adequate supply of our active pharmaceutical ingredients from third party manufacturers on whom the company depends; our inability to obtain additional capital on acceptable terms, or at all; unexpected cost increases and pricing pressures;

uncertainties of cash flows and inability to meet working capital needs; and risks and other risk factors detailed in our public filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K filed on March 23, 2016. Except as otherwise noted, these forward-looking statements speak only as of the date of this press release and we undertake no obligation to update or revise any of these statements to reflect events or circumstances occurring after this press release. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release.

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