Akari Therapeutics Announces Positive Interim Update from Phase Ib Trial Demonstrating Sustained Complement Inhibition Using Once-Daily Subcutaneous Maintenance Dosing with Coversin

NEW YORK and LONDON, July 6, 2016 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, clinical-stage biopharmaceutical company, today announced positive interim data from the first cohort in its Phase Ib trial which demonstrates maintenance of complement inhibition using once-daily dosing. The Phase Ib trial in normal healthy volunteers is designed to investigate the maintenance dose of subcutaneous Coversin needed to maintain complement inhibition on a once daily basis. The company believes near-complete complement inhibition is necessary to maintain adequate control in patients with certain conditions including Paroxysmal Nocturnal Hemoglobinuria (PNH) and atypical Hemolytic Uremic Syndrome (aHUS).

“Subcutaneous dosing with Coversin will represent an important advance for patients in complement therapy,” said Dr. Gur Roshwalb, Chief Executive Officer of Akari Therapeutics. “Patients and key opinion leaders have expressed to us their preference for a subcutaneous, self-administered therapy. We will use this dosing regimen in our upcoming Phase II PNH trial.”

In this double-blind, randomized Phase Ib trial, each cohort of six normal healthy volunteers is given either a loading dose of subcutaneous placebo twice a day for two days followed by five days of a single daily placebo dose (n=2) or, in this first cohort, a loading dose of 30 mg of subcutaneous Coversin twice a day for two days followed by five days of a single daily subcutaneous maintenance dose of 30mg (n=4). Data from this first cohort demonstrated that subcutaneous Coversin achieved complete complement inhibition (Elisa CH50 < 8 Eq/ml, lower limit of quantification) within the first day, and demonstrated complete complement inhibition at the end of dosing on day seven. To date, there have been no injection site reactions reported in the trial. One volunteer receiving the Coversin dose stopped dosing on day three due to a non-serious adverse event possibly related to antibiotics administered for meningitis prophylaxis. The trial is being conducted at Hammersmith Medicines Research Ltd, in London. It is expected that further data from this trial will be presented at future scientific forums.

About Akari Therapeutics Plc

Akari is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics to treat orphan autoimmune and inflammatory diseases. Akari’s lead drug, Coversin is a second-generation complement inhibitor that acts on complement component-C5, preventing release of C5a and formation of C5b-9 (also known as the membrane attack complex or MAC). 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 Paroxysmal Nocturnal Hemoglobinuria (PNH), atypical Hemolytic Uremic Syndrome (aHUS), and Guillain Barré syndrome (GBS).

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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