Akari Therapeutics Announces Additional Data from Non-Human Primate Safety Study Demonstrating Equivalent Coversin Efficacy in Both Elisa CH50 and Hemolytic SRBC Assays

NEW YORK and LONDON, January 5, 2016 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, development-stage biopharmaceutical company, announced an update from its 28 day non-human primate (NHP) safety study that Coversin demonstrated complete inhibition of complement C5 whether measured by Elisa CH50 or Sheep Reb Blood Cell (SRBC) lytic assay (see Figure 1 below). The study tested Coversin daily subcutaneous injection for 28 days at a low and high dose versus placebo in 24 non-human primates and demonstrated no safety issues, adverse events or injection site reactions. 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).

Miles Nunn, Chief Scientific Officer of Akari Therapeutics said “At steady state we see comparable complement inhibition in non-human primates dosed subcutaneously once a day with Coversin whether complement activity is measured by Elisa CH50 U Eq/ml assay or sheep red blood cell lytic CH50 assay. We believe the lytic assay provides a more sensitive measure of residual complement activity than the Elisa assay, and these data at steady state show that complement is completely and tightly inhibited in non-human primates given daily Coversin”.

Figure 1

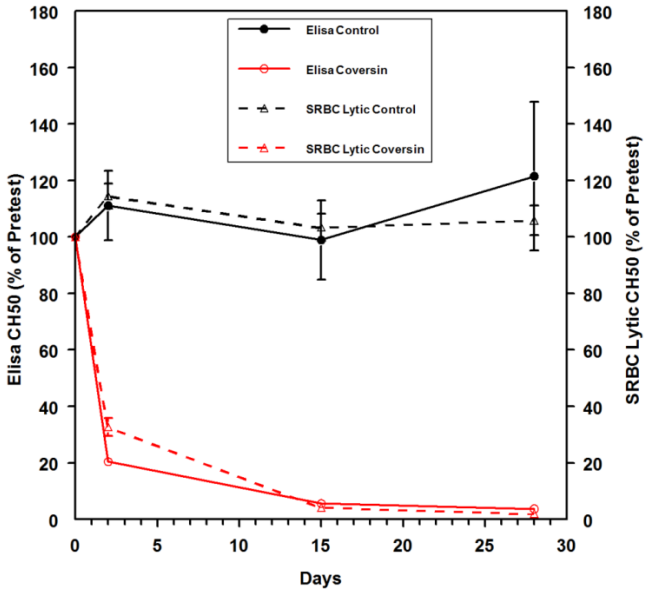

Figure legend: Comparison of the complement activity present in the serum of non-human primates dosed daily with saline control or high dose Coversin and measured by Elisa Quidel CH50 assay or sheep red blood cell (SRBC) lytic CH50 assay. Activity is expressed as the average percentage of complement activity (with CH50 value determined by Elisa or 3-point SRBC lytic assay) at days 2, 15 and 28 compared to baseline (day 0). Vertical bars show standard error of the mean.

“We believe these data demonstrating that Coversin completely inhibited complement C5 activity whether measured by Elisa CH50 or SRBC lytic assays highlights the potential for Coversin to be the best-in-class second generation complement C5 inhibitor in development,” said Gur Roshwalb, Chief Executive Officer of Akari Therapeutics. “The non-human primate safety and complement inhibition data strengthen our belief that daily subcutaneous administration of Coversin in humans at an appropriate dose, to be determined in our upcoming Phase 1b study, should provide the complete and highly stable chronic complement inhibition needed to effectively treat complement driven diseases.”

Full data from this safety study will be presented at a future scientific forum.

About CH50 Testing

CH50 assays measure the activity of the classical complement activation pathway and are sensitive to the reduction, absence and/or inactivity of any component (including inhibited components) of the pathway.

The CH50 assay is often currently performed by an Elisa assay that measures terminal complement complex (TCC) which is formed of complement components C5b-9 (also known as the membrane attack complex or MAC). In the Elisa assay, complement in serum at a single dilution is activated by immunoglobulin either in solution or directly on the ELISA plate leading to formation of TCC. The TCC is captured on the plate and is measured and compared to a series of standards of known TCC concentration. The TCC concentration is described in units of CH50 U Eq/ml and equates directly to a CH50 value determined using the traditional CH50 assay.

The traditional CH50 assay tests the functional capability of serum complement components of the classical pathway to lyse sheep red blood cells (SRBC) pre-coated with rabbit anti-sheep red blood cell antibody (haemolysin). When antibody-coated SRBC are incubated with test serum, the classical pathway of complement is activated and hemolysis results. If a complement component is absent, the CH50 level will be zero; if one or more components of the classical pathway are decreased or inhibited, the CH50 will be decreased. The amount of complement activity is determined by examining the capacity of various dilutions of test serum to lyse antibody coated SRBC. The serum fold-dilution which causes 50% lysis of the SRBC is the CH50 value.

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 product, 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 Quarterly Report on Form 10-Q filed on November 23, 2015. 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.

Contact:
Investor & Media Contact:
Akari Therapeutics Plc
Gur Roshwalb, MD, CEO
646-350-0702
info@AkariTx.com