Akari Therapeutics Receives Approval from the UK Medicines & Healthcare Products Regulatory Agency for Phase IB Multiple Ascending Dose Trial

NEW YORK and LONDON, January 29, 2016 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, development-stage biopharmaceutical company, announced today the approval by the UK Medicines & Healthcare products Regulatory Agency (MHRA) to conduct a Phase IB multiple ascending dose trial. 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).

This Phase IB multiple ascending dose vehicle controlled double-blind trial is designed to determine the maintenance dose of Coversin when given as a daily, fixed-dose, subcutaneous injection that leads to complete inhibition of Complement C5. As demonstrated in our Phase IA single dose trial, a single subcutaneous injection of Coversin at a dose of 0.57mg/kg completely inhibited complement activity by 12 hours in healthy volunteers. In this Phase IB multiple ascending dose vehicle controlled double-blind trial, cohorts of healthy volunteers will receive an ablating dose, followed by 4-6 days of a lower maintenance dose after which complement activity will be measured. The purpose of the trial is to determine the lowest fixed dose at which Coversin completely inhibits complement activity at a 24-hour trough level following the last dose given. Topline results from the trial are expected by the end of the first quarter of 2016 or early second quarter 2016.

“We are very excited to initiate this study and recruit patients,” said Gur Roshwalb, Chief Executive Officer of Akari Therapeutics. “Along with the positive results from our Phase IA study, we believe the data from the Phase IB study and ongoing eculizumab resistance protocol will demonstrate that Coversin has the potential to be the best-in-class second generation complement C5 inhibitor in development.”

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 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.

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