Akari Therapeutics Receives Positive Opinion for Orphan Drug Designation for Coversin in the European Union for Treatment of Guillain Barré Syndrome.

NEW YORK and LONDON, May 23, 2016 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, clinical-stage biopharmaceutical company, announced today that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion recommending orphan drug designation for Coversin for the treatment of Guillain Barré Syndrome (GBS). Coversin, Akari's lead clinical product, 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).

"We are pleased to receive this opinion from COMP, which is our first in Europe," said Dr. Gur Roshwalb, CEO of Akari. "The positive opinion underscores the continued need for the development of new therapies for GBS, where studies show that up to 35% of patients can have long-term neurological complications despite best care. We are excited by our continuing clinical advancement of Coversin and look forward to providing an update on the ongoing Phase Ib once daily subcutaneous multiple dose trial in June, as well as to initiating our Phase II trial in paroxysmal nocturnal hemoglobinuria this summer."

Guillain Barré syndrome is an acute immune-mediated post infectious polyneuropathy where the immune system is triggered into attacking peripheral nerves, leading to progressive, fairly symmetric muscle weakness and paralysis accompanied by absent or depressed deep tendon reflexes. In animal models of GBS, Coversin has been shown to provide protection against such effects.

The COMP adopts an opinion on the granting of orphan drug designation, after which the opinion is submitted to the European Commission (EC) for decision. Orphan drug designation by the EC provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the EU, and where no satisfactory treatment is available. In addition to a 10-year period of marketing exclusivity in the EU if regulatory approval of the drug is ultimately received for the designated indication, orphan drug designation provides incentives for companies seeking protocol assistance from the EMA during the product development phase, and direct access to the centralized authorization procedure. The receipt of orphan drug designation status does not change the regulatory requirements or process for obtaining marketing approval and designation does not mean that marketing approval will be received.

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.

Contact:

Investor & Media Contact:
The Trout Group
Tricia Truehart
ttruehart@troutgroup.com
646–378–2953