Akari Therapeutics Announces Receipt of Orphan Drug Designation for Coversin from the U.S. FDA for Treatment of Paroxysmal Nocturnal Hemoglobinuria

NEW YORK and LONDON, September 12, 2016 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, development-stage biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has granted to Akari an Orphan Drug Designation for recombinant protein inhibitor of complement factor 5 for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH). Coversin, Akari's lead clinical product, which falls within the Orphan Drug Designation, 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).

PNH is an ultra-rare, life-threatening and debilitating disease of the blood with an estimated 8,000-10,000 patients across North America and Europe. Due to an acquired genetic deficiency, uncontrolled complement activation in PNH patients allows their own complement system to attack and destroy blood cells, leading to life-threatening complications.

"We are pleased to receive Orphan Drug Designation in the United States for PNH, and now have this designation for PNH and Guillain Barre Syndrome, or GBS, in the US and EU" said Dr. Gur Roshwalb, CEO of Akari. "We have continued to see complete complement inhibition and symptom control in a PNH patient with resistance to eculizumab, who has been self-administering subcutaneous Coversin for over 7 months. We believe that Coversin, when approved,could provide important benefits for all patients with PNH."

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at the time of designation. Orphan Drug Designation provides the sponsor certain benefits and incentives, including a period of marketing exclusivity if regulatory approval of the drug is ultimately received for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants, and the waiver of certain administrative fees. 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.

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