Akari Therapeutics Announces FDA Allowance of IND for Clinical Development of Coversin in PNH

Phase II trial in eculizumab resistant PNH expected to expand into US

NEW YORK and LONDON, January 3rd, 2017 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, clinical-stage biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has allowed on December 29th, 2016, its Investigational New Drug Application (IND) for the clinical development of Coversin™ in patients with PNH. The FDA's allowance of the IND permits the Company to expand its clinical program for the development of Coversin in PNH to the United States. The Company has one currently treated eculizumab resistant PNH patient who has been on Coversin for approximately 11 months pursuant to an approved clinical protocol in the Netherlands and plans to open this ongoing Phase II trial of Coversin in eculizumab resistant PNH in the United States.

“We are very excited to expand our Phase II program into the United States,” said Dr. Gur Roshwalb, Chief Executive Officer of Akari Therapeutics. “Along with the currently treated eculizumab resistant PNH patient, as well as data from our ongoing Phase II trial in PNH, we expect the results of these trials will help us better understand the effect of Coversin in PNH and prepare us for our Phase III clinical program, which we expect to begin in the summer of 2017.”

The objectives of this clinical trial are to determine the safety and efficacy of Coversin in patients with proven resistance to eculizumab due to complement C5 polymorphisms. These patients are entered into an open label protocol where safety and efficacy are measured on an ongoing basis. Data from patients in this trial will be presented at future scientific forums. Akari also has an ongoing Phase II trial in Europe in patients with PNH without polymorphism with data expected in the first quarter of 2017.

About Akari Therapeutics Plc

Akari is a clinical-stage biopharmaceutical company focused on the development and commercialization of life-transforming treatments for a range of rare and orphan autoimmune and inflammatory diseases caused by dysregulation of complement C5 and Leukotriene B4 (LTB4), including paroxysmal nocturnal hemoglobinuria (“PNH”), atypical Hemolytic Uremic Syndrome (“aHUS”), and Guillain Barré syndrome (“GBS”). Akari’s lead product candidate, Coversin™ complement inhibitor, a second-generation complement inhibitor, acts on complement component-C5, preventing the release of C5a and the formation of C5b–9 (also known as the membrane attack complex or MAC), and independently also inhibits LTB4 activity. 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 PNH, aHUS, and GBS. Exploiting the power of nature, Akari is also developing other tick derived proteins and expects to bring additional compounds to clinical trials over the next several years. The pipeline is focused on developing bioengineered versions of native tick salivary proteins that act as anti-inflammatory compounds allowing the tick to remain on its host. These compounds include PGP sparing LTB4 inhibitors, classical and alternative complement inhibitors, anti-histamines, and serotonin inhibitors as examples. Akari is also developing engineered forms that allow for potential oral absorption, as, for example, a potential orally absorbed C5 inhibitor, and tissue specific proteins, as, for example, Coversin™ that acts specifically at the neuromuscular junction for diseases like myasthenia gravis.

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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