Akari Therapeutics Announces Corporate Update with New Positive Clinical Data and a New Pipeline of Tick Derived and Engineered Proteins

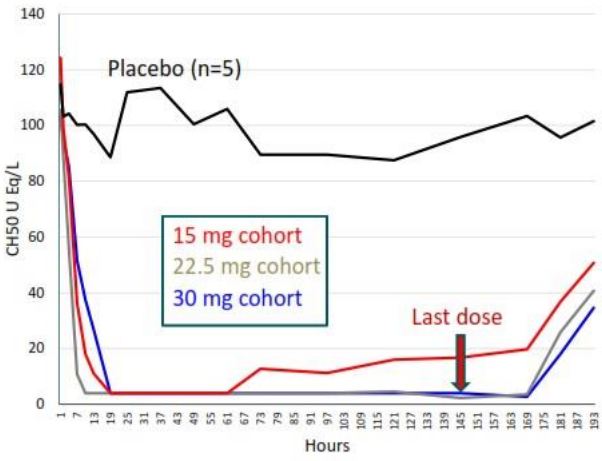
- Phase Ib cohorts demonstrate dose effect and additional support for once daily dosing-
-PAS-Coversin pre-clinical data supports once weekly dosing-
-Phase II PNH patients identified with data expected 1Q17-
-Eculizumab resistant PNH patient treated for over 9 months with Coversin-
-New pipeline of tick derived and engineered proteins-
-Coversin engineered protein targeting neuromuscular junction for myasthenia gravis-
-Proteins targeting two additional pathways as well as second complement inhibitor-

NEW YORK and LONDON, December 5th, 2016 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, clinical-stage biopharmaceutical company, announced several corporate updates that were discussed during an Analyst & Investor Symposium held during the 58th American Society of Hematology meeting. The corporate presentation is available at http://akaritx.com/event/ash-analyst-investor-symposium/.

Clinical Update

Phase Ib

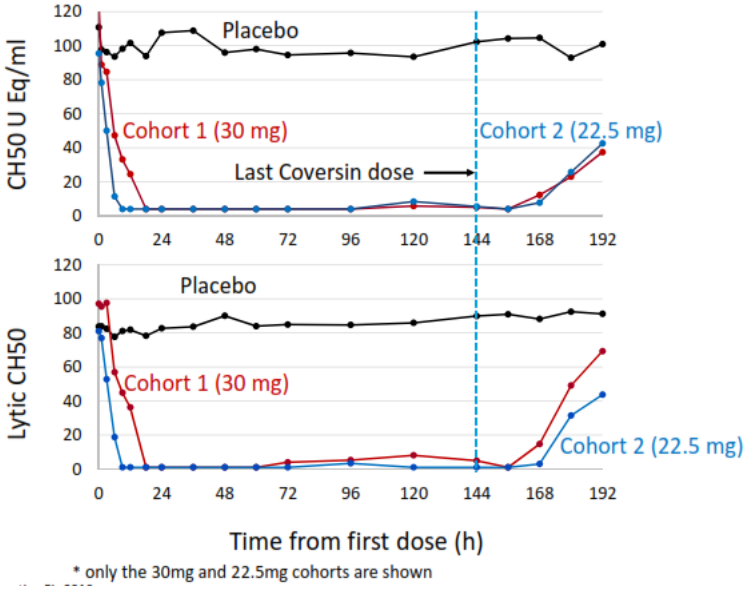
Data from additional cohorts (15mg and 22.5mg daily maintenance cohorts) of the ongoing Phase Ib trial of Coversin in healthy volunteers showed a dose effect and demonstrated that the 22.5 mg maintenance dose also supports once daily dosing, as does the 30 mg maintenance dose as reported previously.



CH50 below 8.0 is lower than limit of quantitation so mean of these results shown (4.0 U Eq/L)

In this double-blind, randomized Phase Ib trial, each cohort of six normal healthy volunteers is given either a loading dose of subcutaneous placebo twice a day for two days followed by five days of a single daily placebo dose (n=2) or a loading dose of 30 mg of subcutaneous Coversin twice a day for two days followed by five days of a single daily subcutaneous maintenance dose (n=4). Data from the 22.5 mg once daily maintenance cohort demonstrated that subcutaneous Coversin achieved complete complement inhibition (Elisa CH50 < 8 Eq/ml, lower limit of quantification) within the first day, and

demonstrated complete complement inhibition at the end of dosing on day seven whether measured using the ELISA or lytic CH50 assays.



The data from the 15 mg once daily maintenance cohort demonstrated that subcutaneous Coversin achieved complete complement inhibition (Elisa CH50 < 8 Eq/ml, lower limit of quantification) within the first day but by day three was unable to maintain complete complement inhibition at the 24-hour trough measurement. There have been no injection site reactions reported in the trial.

“These data support once daily dosing with Coversin,” said Miles Nunn, PhD, Chief Scientific Officer at Akari. “Demonstration of a dose effect and concordance between the ELISA CH50 and Lytic Ch50 assays was in-line with expectation.”

PAS-Coversin

PASylation® entails modifying Coversin, a recombinant small protein (17kDa), by adding a 600 amino acid proline/alanine/ serine (PAS) N-terminal fusion tag to generate PAS-Coversin (68kDa). The unstructured and uncharged PAS polypeptide increases the apparent molecular size to approximately 720kDa, slowing kidney clearance and extending the half-life.

Data from mouse and rat studies of PAS-Coversin demonstrated that the expected terminal half-life in humans should be approximately 4 days. Based on these data, Pk modeling supports that a once weekly dosing regimen is feasible. Akari expects first in man trials to begin in the fourth quarter of 2017.

Eculizimab-resistant PNH Patient

As reported previously, an eculizumab-resistant PNH patient had been under treatment with subcutaneous Coversin for nine months under an approved clinical protocol. The patient continues to self-administer Coversin and continues to demonstrate complete complement inhibition without any change in dose or injection site reactions. The patient’s most recent reported LDH was below 300. Further, there have been no signs of neutralizing antibodies.

Phase II
In the ongoing PNH Phase II trial, investigators have identified all trial patients. Akari expects to release data on these patients in the first quarter of 2017.

New Pipeline of Tick Derived and Engineered Proteins

Platform of Tick Derived and Engineered Proteins
Akari introduced its discovery program of tick derived anti-inflammatory proteins. The pipeline includes a wide range of new and engineered proteins including a second and potentially orally available C5 inhibitor, compounds binding LTB4, histamine, serotonin and other parts of the inflammatory pathway, and tissue targeting compounds including a Coversin specific to the neuromuscular junction (NMJ) for conditions like myasthenia gravis. This tissue targeted form of Coversin has the potential to specifically inhibit complement only at the NMJ and not systemically and is targeted for first in human trials in the first half of 2018. Additional details on the new anti-inflammatory molecules will be provided as early as 1Q17.

"We remain focused on completing our Phase PNH II study and preparing for our Phase III studies targeted for the summer of 2017," said Dr. Gur Roshwalb, CEO of Akari. "With the rich potential pipeline of therapies available from our platform, both exploiting the power of nature and the ability to take the platform further by modifying these proteins, we also look forward to advancing new compounds into the clinic and bringing innovative therapies for orphan and unmet diseases."

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, both native and engineered and expects to bring additional compounds to clinical trials over the next several years.

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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