

Akari Therapeutics Announces Regulatory Progress Following FDA Meeting

Plans to start Coversin Phase III in PNH in Q1 2018

NEW YORK and LONDON, September 21, 2017 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), a biopharmaceutical company focused on the development and commercialization of innovative therapeutics to treat orphan autoimmune and inflammatory diseases, announces that, following advice from a recent FDA Type B End of Phase II Meeting, it plans to advance its lead investigational drug, Coversin™, towards Phase III clinical studies in Paroxysmal Nocturnal Hemoglobinuria (PNH) in Q1 2018.

“Following our recent FDA meeting, we are working to initiate a Phase III clinical trial of Coversin in PNH in Q1 2018,” said Dr. David Horn Solomon, Chief Executive Officer of Akari Therapeutics. “We will continue to work closely with the FDA, benefitting from our Fast Track status in the U.S., and with the EMA towards submission of a BLA and MAA, respectively, for Coversin in PNH.”

Akari plans to carry out two Phase III clinical studies: CAPSTONE, in naïve PNH patients where eculizumab (Soliris®; Alexion) is not the standard of care, with co-primary clinical endpoints based on hemoglobin and transfusion data, and ASSET, a Phase III clinical study switching PNH patients from eculizumab, the current standard of care treatment in PNH in the U.S., to treatment with Coversin.

The FDA indicated that providing safety and efficacy data from the Company’s clinical trials for the proposed number of unique PNH patients on Coversin for more than one year seems reasonable, subject to review of the actual data upon submission. The number proposed includes patients having C5 polymorphisms conferring eculizumab resistance.

“Akari continues to build momentum in its complement focused therapy by advancing Coversin towards Phase III in PNH and Phase II in aHUS. With Coversin delivered subcutaneously, patients may have greater independence due to self-administration. Phase II studies are also planned for a number of other indications where Coversin’s actions on both the complement and leukotriene (LTB4) pathways play a role. Its two leading targets in this area are atopic keratoconjunctivitis (AKC), a rare eye disorder and severe bullous pemphigoid (BP), a rare skin disorder,” added Solomon.

About Akari Therapeutics

Akari is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics to treat orphan autoimmune and inflammatory diseases, in particular those where the complement system or leukotrienes or both complement and leukotrienes together play a primary role in disease progression. Akari’s lead drug candidate Coversin is a C5 complement inhibitor currently being evaluated in paroxysmal nocturnal hemoglobinuria (PNH) and atypical

hemolytic uremic syndrome (aHUS). In addition to its C5 inhibitory activity, Coversin independently and specifically inhibits leukotriene B4 (LTB4) activity. Akari intends to evaluate Coversin in two conditions, the skin and eye diseases bullous pemphigoid and atopic keratoconjunctivitis, where the dual action of Coversin on both C5 and LTB4 may be beneficial. Akari is also developing other tick derived proteins, including long acting versions.

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: needs for additional capital to fund our operations, 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 20-F filed on March 31, 2017. 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.
For more information

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