Akari Therapeutics Plc and XL-protein GmbH Sign License Agreement to Develop a Long Acting Version of Coversin Using PASylation® Technology

NEW YORK, LONDON, and FREISING, Germany, April 14, 2016 (GLOBE NEWSWIRE) -- Akari Therapeutics (NASDAQ: AKTX), an emerging growth, development-stage biopharmaceutical company, and XL-protein, a privately owned biopharmaceutical company, announced today that they have entered into a License, Development and Commercialization Agreement. This partnership is focused on developing a second generation, longer acting version of Coversin.

Under this collaboration agreement, XL-protein will apply its proprietary PASylation® technology for drug half-life extension to Coversin. 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).

XL-protein has previously demonstrated that it can manufacture recombinant PASylated Coversin. An initial study conducted in a mouse model indicates that PASylated Coversin administered by subcutaneous injection remains fully active, with the high C5 binding activity of Coversin retained. In this study, it was found that PASylation of Coversin extended the plasma half-life by over 50 fold.

“XL-protein’s PASylation technology provides an elegant approach to extending the half-life of Coversin, which we hope to demonstrate in future studies will reduce the frequency of dosing,” said Miles Nunn, Chief Scientific Officer of Akari Therapeutics. “Our current plan is to investigate the relative performance of PASylated Coversin, administered by the subcutaneous route, in animal models of disease. If successful, we expect to progress PASylated Coversin to the clinic.”

“We are delighted to enter into the partnership with Akari Therapeutics; the data from the initial study indicate that PASylation could lead to a longer acting, less frequently dosed, subcutaneous version of Coversin”, commented Claus Schalper, Chief Executive Officer of XL-protein. “XL-protein successfully continues to add collaborations with renowned partners that can leverage our best-in-class half-life extension technology.”

Under the terms of the agreement, XL-protein will receive an upfront payment as well as payments for achievement of preclinical, clinical, regulatory and commercial milestones. Furthermore, XL-protein will receive royalties on sales from marketed compounds resulting from the collaboration. Further financial terms have not been disclosed.

About XL-protein GmbH

XL-protein is a German biotech company commercializing the ground-breaking PASylation® technology, which enables the design of biopharmaceuticals with extended plasma half-life and enhanced action. With its strong proprietary technology position XL-protein focuses at the preclinical as well as clinical development of PASylated proteins in various disease areas. The company is located at Freising, Germany, in the neighbourhoods of Munich International Airport and the Technical University of Munich. (www.xl-protein.com)
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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