
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

August 2019

Commission file number: 001-36288

Akari Therapeutics, Plc
(Translation of registrant's name into English)

75/76 Wimpole Street
London W1G 9RT
United Kingdom
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7): _____

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On August 14, 2019, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that the US Food and Drug Administration has granted Fast Track designation for nomacopan for the treatment of hematopoietic stem cell transplant associated thrombotic microangiopathy (HSCT-TMA) in pediatric patients. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

In addition, on August 13, 2019, Dov Elefant notified the Company of his decision to resign as Chief Financial Officer of the Company, after over 7 years with the Company, in order to accept another opportunity. Mr. Elefant has agreed to assist in the smooth transition of his duties and his last day is expected to be in mid-September. The Company thanks Mr. Elefant for his many years of service and contributions to the Company.

The information in this Form 6-K including the first paragraph of Exhibit 99.1 is hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933.

Exhibit No.

99.1 Press Release dated August 14, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Akari Therapeutics, Plc
(Registrant)

By: /s/ Clive Richardson
Name: Clive Richardson
Interim Chief Executive Officer and
Chief Operating Officer

Date: August 14, 2019

Akari Therapeutics Receives FDA Fast Track Designation for Nomacopan for Paediatric Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA)

- *Fast Track designation by the U.S. Food and Drug Administration (FDA) facilitates the development and expedites the review of new medicines like nomacopan that treat serious unmet medical needs and in Akari's case, pediatric patients with HSCT-TMA.*
- *The Fast Track designation follows a successful pre-investigational new drug (IND) FDA meeting earlier this year regarding Akari's proposed pivotal clinical trial program for HSCT-TMA.*
- *The FDA is working with Akari in its optimization of pediatric dosing for HSCT-TMA by Akari's participation in the FDA Model-Informed Drug Development (MIDD) Program with supportive PK data provided by pediatric patients already treated with nomacopan as part of a named patient program.*
- *Proposed pivotal trial of nomacopan in pediatric patients with HSCT-TMA expected to start Q4 2019 in North America and Europe.*

NEW YORK and LONDON, August 14, 2019 – Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement and/or leukotriene systems are implicated, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for nomacopan for the treatment of hematopoietic stem cell transplant associated thrombotic microangiopathy (HSCT-TMA) in pediatric patients. The Fast Track designation supports Akari's plans for expedited approval of nomacopan for HSCT-TMA, with the pivotal trial expected to commence in the fourth quarter of 2019.

Fast Track designation is intended to facilitate the development and expedite the review of new drugs which show promise in treating serious or life-threatening conditions and address unmet medical needs. Drugs that receive this designation benefit from more frequent communications and meetings with FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with Fast Track designation may qualify for priority review to expedite the FDA review process, if relevant criteria are met.

HSCT-TMA is an orphan condition with an estimated fatality rate of more than 80% in children with the severe disease. There are currently no approved treatments for HSCT-TMA but there is strong evidence for the role of complement and potentially LTB4 in the etiology of the disease.

In September 2018, Akari announced that in the first two HSCT-TMA patients treated with nomacopan as part of a UK named patient program, it had observed disease resolution by way of a rapid reduction of the markers of complement activation as well as normalization of markers that are elevated in HSCT-TMA patients (platelet count, red blood cell fragments, thrombocytopenia, elevated LDH and hypertension). On the basis of existing treatment data from these HSCT-TMA patients and a further 20 cumulative patient-years of data from other patients treated with nomacopan, Akari is working with the FDA Model Informed Drug Development (MIDD) Program to optimize the pediatric dosing with nomacopan for the planned pivotal HSCT-TMA trial.

Clive Richardson, interim CEO of Akari Therapeutics, said, “Fast Track designation provides our HSCT-TMA clinical program a pathway for an expedited approval for nomacopan, and we plan to commence a pivotal trial in the fourth quarter of 2019. We see HSCT-TMA as a gateway into a range of other poorly treated orphan TMAs in both pediatric and adult patients, and are optimistic about the potential for nomacopan to offer an improved standard of care for these orphan conditions with high mortality rates.”

About Akari Therapeutics

Akari is a biopharmaceutical company focused on developing inhibitors of acute and chronic inflammation, specifically for the treatment of rare and orphan diseases, in particular those where the complement (C5) or leukotriene (LTB4) systems, or both complement and leukotrienes together, play a primary role in disease progression. Akari's lead drug candidate, nomacopan (formerly known as Coversin), is a C5 complement inhibitor that also independently and specifically inhibits leukotriene B4 (LTB4) activity. Nomacopan is currently being clinically evaluated in four indications: bullous pemphigoid (BP), atopic keratoconjunctivitis (AKC), thrombotic microangiopathy (TMA), and paroxysmal nocturnal hemoglobinuria (PNH). Akari believes that the dual action of nomacopan on both C5 and LTB4 may be beneficial in AKC, BP and other orphan inflammatory conditions. Akari is also developing other tick derived proteins, including longer 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, our ability to continue as a going concern; uncertainties of cash flows and inability to meet working capital needs; an inability or delay in obtaining required regulatory approvals for nomacopan and any other product candidates, which may result in unexpected cost expenditures; our ability to obtain orphan drug designation in additional indications; risks inherent in drug development in general; uncertainties in obtaining successful clinical results for nomacopan and any other product candidates and unexpected costs that may result therefrom; difficulties enrolling patients in our clinical trials; failure to realize any value of nomacopan 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 nomacopan may not be as large as expected; risks associated with the departure of our former Chief Executive Officers and other executive officers; risks associated with the SEC investigation; 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; unexpected cost increases and pricing pressures and risks and other risk factors detailed in our public filings with the U.S. Securities and Exchange Commission, including our most recently filed Annual Report on Form 20-F filed with the SEC. 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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