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

December 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 December 2, 2019, Akari Therapeutics, Plc (the "Company") issued a press release announcing the design of a pivotal Phase III pediatric trial in Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA) following a U.S. Food and Drug Administration (FDA) End-of-Phase II meeting. The Company also announced that, in another hematological condition, all six patients from the long-term Phase II Paroxysmal Nocturnal Hemoglobinuria (PNH) study who were transfusion dependent at entry are now transfusion independent on long-term treatment with nomacopan. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in paragraphs one and two 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 December 2, 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
Chief Executive Officer and
Chief Operating Officer

Date: December 2, 2019

Exhibit 99.1

Akari Therapeutics Announces Pivotal Phase III Trial Design of Nomacopan in Pediatric Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA), Following FDA Meeting

Update on Paroxysmal Nocturnal Hemoglobinuria (PNH) Long Term Safety Study Shows 100% Transfusion Independence

- *Two-part pivotal Phase III study of nomacopan in pediatric patients with HSCT-TMA based on guidance from End-of-Phase II meeting with U.S. Food and Drug Administration (FDA):*
  - *Part A dose confirmation study. Dosing scheme has been agreed with the FDA through Akari's participation in the Model Informed Drug Development (MIDD) Program.*
  - *Part B single arm responder-based efficacy study will follow an interim analysis of Part A and a meeting with the FDA.*
- *Phase III HSCT-TMA study expected to open by the end of Q4 2019.*
- *HSCT-TMA program has received both orphan and Fast Track designations from the FDA.*
- *New data from ongoing long-term PNH study shows that all six patients from the Phase II study who were transfusion dependent at entry are now transfusion independent on nomacopan.*

NEW YORK and LONDON, December 2, 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, announces the design of a pivotal Phase III pediatric trial in HSCT-TMA following a FDA End-of-Phase II meeting. Akari also announces that, in another hematological condition, all six patients from the long-term Phase II PNH study who were transfusion dependent at entry are now transfusion independent on long-term treatment with nomacopan.

HSCT-TMA is an orphan hematological condition with no approved treatments and an estimated mortality rate of more than 80% in children with the severe form of the disease[1]. It is this severe form that is being targeted with nomacopan. Following a recent End-of-Phase II meeting with the FDA, Akari plans to initiate a single arm responder-based study design, based on treatment with nomacopan for up to 24 weeks. The primary endpoints are focused on disease response defined primarily by renal improvement and reduced transfusion dependence. The study will be in two parts, with data from seven patients in Part A used to confirm dosing and endpoints for Part B, with the pharmacokinetic (PK) modelling agreed with the FDA through Akari's participation in the Model Informed Drug Discovery Program (MIDD). Following an interim efficacy and safety readout from Part A and meeting with the FDA, patients would then be recruited into Part B of the responder study.

While the role of complement inhibition is understood to play an important role in HSCT-TMA, LTB4 may also be an important target in reducing epithelial activation in both TMA and graft versus-host disease[2] (GVHD) which often occur simultaneously. Daily dosing with nomacopan is also likely to be of a particular advantage in facilitating more complete complement suppression, especially in HSCT-TMA patients with high transfusion requirements.

HSCT-TMA is Akari's second haematological clinical program and follows a successful Phase II study in PNH completed in early 2018, after which patients continued treatment with nomacopan in a long-term safety study. New data from Akari's ongoing long-term study, shows that all six patients from the Phase II study who were transfusion dependent at entry are now transfusion independent on nomacopan, having had in all cases no transfusions for a minimum of six months. In addition, during more than 20 cumulative patient-years of PNH patient treatment with nomacopan, there have been no reported drug-related serious adverse events.

"Following our meeting with the FDA, we look forward to starting the pivotal Phase III study of nomacopan in HSCT-TMA, a potential treatment for a high risk pediatric population which currently has no approved therapies. If successful, we expect this will be a gateway indication into a range of other poorly treated orphan TMAs," commented Clive Richardson, CEO Akari Therapeutics. "We are pleased with the progress being made across our clinical studies where recent positive clinical data in bullous pemphigoid (BP) and PNH provides further support for the underlying efficacy of nomacopan."

1 Sonata Jodele, et al. New approaches in the diagnosis, pathophysiology, and treatment of pediatric hematopoietic stem cell transplantation associated thrombotic microangiopathy. Transfus Apher Sci . 2016 April; 54(2): 181–190

2 Takatsuka, et al. Predicting the severity of intestinal graft-versus-host disease from leukotriene B4 levels after bone marrow transplantation. Transplantation 2000, 26: 1313-1316

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). 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 and BP. 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 regarding, among other things, statements related to the offering, the expected gross proceeds and the expected closing of the offering. 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; our ability to enter into collaborative, licensing, and other commercial relationships and on terms commercially reasonable to us; 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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