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 23, 2019, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that a U.S. Food and Drug Administration (FDA) investigational new drug application (IND) is open for its multicentre Phase III study for the treatment of paediatric Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA) with nomacopan, allowing clinical sites to open in the first quarter of 2020. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in paragraphs one and three 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 23, 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
Title: Chief Executive Officer and Chief Operating Officer

Date: December 23, 2019

Exhibit 99.1

Akari Therapeutics Announces Initiation of Pivotal Phase III Trial of Nomacopan in Pediatric Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA) Following the Opening of its IND

NEW YORK and LONDON, December 23, 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 that a U.S. Food and Drug Administration (FDA) investigational new drug application (IND) is open for its multicenter Phase III study for the treatment of pediatric HSCT-TMA with nomacopan, allowing clinical sites to open in the first quarter of 2020.

“With the pediatric HSCT-TMA IND now open we look forward to starting the pivotal Phase III study of nomacopan in HSCT-TMA, a potential treatment for a high risk pediatric population that suffer very high death rates and for which there are currently no approved therapies. If successful, we expect HSCT-TMA to be a gateway into a range of other poorly treated orphan TMAs,” commented Clive Richardson, CEO of Akari Therapeutics. “In addition, following the recent successful completion of our Phase II bullous pemphigoid study, we expect data from our Phase I/II atopic keratoconjunctivitis trial in early 2020 and interim data from our Phase III paroxysmal nocturnal hemoglobinuria trial in the first half of 2020.”

HSCT-TMA is an orphan hematological condition that occurs in up to 30% of patients who have received a hematopoietic stem cell transplant (HSCT). There are no approved treatments for pediatric HSCT-TMA, and it has 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 which is a bifunctional inhibitor of complement C5 and leukotriene B4 (LTB4). Following the recent end-of-Phase II meeting with the FDA, Akari has now opened an IND to initiate its pivotal pediatric HSCT-TMA study based on a single arm responder-based design. Recruitment will be focused on specialist pediatric sites in the U.S. and Europe where treatment tends to be concentrated in specialist centres.

Whilst the role of complement inhibition is understood to play an important role in pediatric HSCT-TMA, the Company believes 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. The Company believes daily dosing with nomacopan may also be of particular advantage in facilitating more complete complement suppression, especially in HSCT-TMA patients with high transfusion requirements.

As previously announced, this two-part pivotal Phase III study of nomacopan in pediatric patients with HSCT-TMA is based on guidance from the Company’s end-of-Phase II meeting with the FDA. Part A of the trial is a dose confirmation study. Part B of the trial is a single arm responder-based efficacy study that will follow an interim analysis of Part A and a meeting with the FDA. Akari has both FDA fast track and orphan status for this program.

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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