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

July 2022

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 July 7, 2022, Akari Therapeutics, Plc (the “Company”) issued a press release announcing the first patient to complete course of treatment in the phase III part A clinical trial of investigational nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA).

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in paragraphs one, two, four, six, seven and eight are hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933.

Exhibit No.

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/ Rachelle Jacques
Name: Rachelle Jacques
President and Chief Executive Officer

Date: July 7, 2022

Exhibit 99.1

Akari Therapeutics Announces First Patient to Complete Course of Treatment in the Phase III Part A Clinical Trial of Investigational Nomacopan in Pediatric Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA)

NEW YORK and LONDON, July 7, 2022 (GLOBE NEWSWIRE) -- Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company focused on developing advanced therapies for autoimmune and inflammatory diseases, today announced that a patient has completed the course of investigational nomacopan treatment in the open-label, multi-center Phase III Part A clinical trial in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). Nomacopan is a bispecific recombinant inhibitor of complement C5 and leukotriene B4 (LTB4).

Three patients with severe (nephrotic range proteinuria and elevated soluble C5b-9) HSCT-TMA have been enrolled in the clinical trial. One patient completed more than 60 days of nomacopan treatment and subsequently was discharged from the hospital. Another patient died from multi-organ failure unrelated to nomacopan treatment. Dosing has begun in the third patient.

“This is promising news for children and families facing hematopoietic stem cell transplant-related TMAs who have unmet needs that are significant and urgent because there are no approved treatment options,” said Rachelle Jacques, President and CEO of Akari Therapeutics. “Recruitment into a study of treatment for a rare and emergent complication of stem cell transplants in children has inherent challenges, and it is testament to the passion and commitment of everyone involved that this important Phase III clinical trial is progressing on behalf of patients and their families.”

Nomacopan was granted Orphan Drug and Fast Track designations by the U.S. Food and Drug Administration (FDA) for pediatric HSCT-TMA. Data from the Phase III Part A study of nomacopan in HSCT-TMA will inform the pivotal Phase III Part B study that will be the basis for potential regulatory submissions in the U.S. and Europe.

The six-year-old patient who was discharged was treated at a clinical trial site in Manchester, England by investigator Rob Wynn, M.D. “Thrombotic microangiopathy following a stem cell transplant procedure is a rare but devastating complication made even more tragic because there are currently no approved treatments,” said Professor Rob Wynn, of Royal Manchester Children’s Hospital, part of Manchester University NHS Foundation Trust. “As we advance this important clinical trial and offer treatment to children in Manchester where formerly there was none, we are bringing new hope to families who are in desperate need, and to other clinicians who very much want to offer a treatment option.”

Thrombotic microangiopathy following a stem cell transplant procedure is a rare but serious complication of HSCT that appears to involve complement activation, inflammation, tissue hypoxia and blood clots, leading to progressive organ damage and death. The mortality rate in patients who develop severe transplant-related TMAs is 80%.[1] Currently, there are no approved treatment options in the U.S. or Europe.

Sites are open and recruiting in the U.S, U.K., and Poland for the Phase III Part A clinical trial of investigational nomacopan in pediatric patients who have undergone allogeneic or autologous HSCT and develop HSCT-TMA within a year of transplant. Patient dosing is underway in the multi-center, open-label study that has a recruitment goal of seven pediatric patients over six months old.

The primary study endpoints are either independence of red blood cell transfusion or urine protein creatinine ratio of 2 mg/mg maintained over 28 days immediately prior to any scheduled clinical visit up to Week 24. According to the study protocol, patients may discontinue therapy sooner than 24 weeks, if one, or both, of the primary endpoint components has been met and the treating clinician determines there is no longer a need for continued treatment with nomacopan. Patients who have achieved the primary endpoint and are no longer receiving nomacopan will have a follow-up clinic visit 30 days after the last dose, at 24 weeks and for long-term follow-up at one and two years.

References

1. Rosenthal J. Hematopoietic cell transplantation-associated thrombotic microangiopathy: a review of pathophysiology, diagnosis, and treatment. J Blood Med. 2016;7:181-186. Published 2016 Sep 2. doi:10.2147/JBM.S102235

About Akari Therapeutics

Akari Therapeutics, plc (Nasdaq: AKTX) is a biotechnology company focused on developing advanced therapies for autoimmune and inflammatory diseases. Akari's lead asset, investigational nomacopan, is a bispecific recombinant inhibitor of C5 complement activation and leukotriene B4 (LTB4) activity. The Akari pipeline includes two late-stage programs for bullous pemphigoid (BP) and thrombotic microangiopathy (TMA), as well as earlier stage research and development programs in eye and lung diseases with significant unmet need. For more information about Akari, please visit akaritx.com.

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 there; 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 impact of the COVID-19 pandemic; 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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