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

For the month of: February 2023

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 ☐

On February 21, 2023, Akari Therapeutics, Plc, a public company with limited liability incorporated under the laws of England and Wales (the "Company"), issued a press release announcing the presentation of a patient case study from the Phase 3 Part A clinical trial of nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy. A copy of such press release is furnished as Exhibit 99.1 to this Report on Form 6-K and incorporated herein by reference.

The information in the first, second and fourth paragraphs of such press release are hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933, as amended.

Exhibit No.	
99.1	Press Release issued by Akari Therapeutics, Plc on February 21, 2023.

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
Title: President and Chief Executive Officer

Date: February 21, 2023

Exhibit 99.1

Akari Therapeutics Announces Presentation of a Case Study from Phase 3 Part A Clinical Trial of Nomacopan in Pediatric HSCT-TMA as a Late-Breaker at The Transplantation & Cellular Therapy Tandem Meetings

NEW YORK and LONDON, Feb. 21, 2023 (GLOBE NEWSWIRE) -- Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company developing advanced therapies for autoimmune and inflammatory diseases, today announced the late-breaker presentation of a patient case study from the Phase 3 Part A clinical trial of nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). The case study, *Clinical Response to Nomacopan in the Pediatric HSCT-TMA Setting*, was presented on Thursday February 16, at 5:45 pm ET at the Transplantation & Cellular Therapy Tandem Meetings in Orlando, Florida. Nomacopan is an investigational bispecific inhibitor of both complement C5 and leukotriene B4 (LTB4).

A 6-year-old male patient at Royal Manchester Children's Hospital, Manchester University NHS Foundation Trust in Manchester, United Kingdom (a Phase 3 Part A clinical trial site) received a 6/8 HLA-mismatched unrelated cord blood HSCT conditioned with fludarabine, treosulfan and thiotepa, for relapsed refractory acute myelogenous leukemia (AML). The patient received 7 granulocyte infusions peri-transplant as part of an experimental protocol to augment the graft-versus-leukemia effect. His immediate post-transplant course was complicated by engraftment syndrome, acute gut graft-versus-host disease (GVHD) grade 3 and cytomegalovirus (CMV) viraemia. At day +66 after transplant, the patient developed features consistent with TMA, was enrolled in the Phase 3 Part A clinical trial, and began treatment with nomacopan on day +74. A single-age and weight-based ablating dose was followed by maintenance dosing for 21 days.

The patient was treated by investigator Professor Rob Wynn, M.D. "Although this is one case study and there is a great deal more we must do in this clinical trial, I am optimistic we are bringing new hope for a potential treatment option to children and their families who are in desperate need," said Professor Wynn of Royal Manchester Children's Hospital, part of Manchester University NHS Foundation Trust.

After initial pharmacodynamic analysis at day 14 of treatment, the patient was found to have pre-dose terminal complement activity (TCA) slightly higher (value 14.4) than the LLOQ (CH50 >10 U Eq/ml). Although his TCA had been reduced by 95% from a high baseline CH50 of 299.6U Eq/ml and sC5b9 had normalized, dose was increased in line with the study protocol. A few days later the patient developed neurological symptoms following a period of hypertension and was diagnosed with posterior reversible encephalopathy syndrome (PRES). Nomacopan was stopped for 3 days and restarted after the diagnosis was deemed to be unrelated to nomacopan treatment. Treatment continued for 46 days until the patient's urine protein creatinine ratio was corrected for ≥28 days. Gut pathology and thrombocytopenia were resolved. The patient was discharged from the hospital and remains well and in remission. No adverse events related to nomacopan were experienced during the 72-day treatment period.

"While I have not been part of this important clinical trial, I applaud the efforts of investigators to research and potentially bring forward a studied, approved treatment option with simple dosing that is validated for use in a pediatric critical care setting," said Sonata Jodele, M.D., Research Professor in the Division of Bone Marrow Transplantation and Immune Deficiency at the University of Cincinnati Department of Pediatrics.

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.

The Transplantation & Cellular Therapy Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) is the premier medical conference for the field of bone marrow transplant and cellular therapy.

A poster of the case study is available at http://investor.akaritx.com/news-and-events/presentations.

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 developing advanced therapies for autoimmune and inflammatory diseases. Akari's lead asset, investigational nomacopan, is a bispecific recombinant inhibitor of complement C5 activation and leukotriene B4 (LTB4) activity. Akari's pipeline includes a Phase 3 clinical trial program investigating nomacopan for severe pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). Akari has been granted Orphan Drug, Fast Track and Rare Pediatric Disease designations from the FDA for nomacopan for the treatment of pediatric HSCT-TMA. Akari’s pipeline also includes a clinical program developing nomacopan for adult HSCT-TMA and pre-clinical research of long-acting PAS-nomacopan in geographic atrophy (GA). 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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