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 13, 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 acceleration of the Phase 3 clinical trial of nomacopan for treatment of pediatric HSCT-TMA into pivotal Part B and addition of a new pipeline program developing nomacopan for HSCT-TMA in adults. 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 three and the seventh 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 13, 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 13, 2023

Exhibit 99.1

Akari Therapeutics Announces Acceleration of the Phase 3 Clinical Trial of Nomacopan for Treatment of Pediatric HSCT-TMA into Pivotal Part B and Addition of a New Pipeline Program Developing Nomacopan for HSCT-TMA in Adults

- Based on Type C guidance requested and received from the U.S. Food and Drug Administration (FDA), Akari announces it is moving forward into design and planning for pivotal Part B of the Phase 3 clinical trial of nomacopan for treatment of pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) in pediatric patients between 2 years and <18 years of age

- According to FDA feedback, the PK/PD data from Part A of the clinical trial are consistent with predictions from the latest nomacopan PK/PD model and support moving into Part B in pediatric patients over 2 years of age

- Since enrollment for the youngest age group (aged 0.5 to <2 years) in the Part A study is not complete, Akari is keeping the study open for these young pediatric patients while advancing pivotal Part B study of nomacopan in the older pediatric patients

- Akari also is announcing initiation of a new pipeline program for the development of nomacopan as a potential treatment for adults with HSCT-TMA, which will include a study supportive of the pediatric program; the adult HSCT-TMA population is >10 times the size of the pediatric population

NEW YORK and LONDON, Feb. 13, 2023 (GLOBE NEWSWIRE) -- Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company developing advanced therapies for autoimmune and inflammatory diseases, today announced the Phase 3 clinical trial of nomacopan in pediatric patients with hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) is moving into Part B sooner than expected and the company is beginning the planning and design for the pivotal study in pediatric patients over 2 years of age. Akari also announces it has added a new pipeline program that will develop nomacopan as a potential treatment for adult HSCT-TMA, which will include a study that is supportive of the pediatric program. Study enrollment for the adult program is expected in 2024. Nomacopan is a novel bispecific inhibitor of complement C5 and leukotriene B4 (LTB4) in clinical development for pediatric and adult HSCT-TMA. Long-acting PAS-nomacopan is in pre-clinical development for geographic atrophy secondary to dry age-related macular degeneration.

Part A of the Phase 3 clinical trial of nomacopan in pediatric HSCT-TMA was designed to include three cohorts: ages 0.5 to <2 years, ≥2 to <9 years and ≥9 to <18 years. Akari enrolled patients in the two older age groups and, based on feedback from the FDA, the PK/PD data from these patients from the Part A study are consistent with the predictions derived from Akari's latest PK/PD model. Since enrollment for the youngest age cohort (ages 0.5 to <2 years) in the Part A pediatric study is not completed Akari is keeping the study open for this youngest group of pediatric patients while advancing the pivotal Part B study of nomacopan in the older pediatric patients.

Akari participated in the FDA Model-Informed Drug Development (MIDD) program to refine the Akari PK/PD model suitability and doses for the Phase 3 clinical trial of nomacopan in pediatric HSCT-TMA. Clinical data from 38 subjects (in previous clinical studies and healthy volunteers) were included in the Akari PK/PD model, which was used to predict dosing for pediatric HSCT-TMA patients through 10,000 virtual patient simulations. These informed FDA MIDD interactions that confirmed PK/PD model suitability and doses selected for the nomacopan Phase 3 Part A clinical trial in pediatric HSCT-TMA. An expanded PK/PD model using data from 55 patients treated with nomacopan was reviewed in the recent Type C interaction with the FDA along with PK/PD data from the Part A study. According to FDA feedback, the model is predictive and supports a simple, fixed dosing regimen of nomacopan in the upcoming Phase 3 pivotal Part B clinical trial in pediatric HSCT-TMA patients who are ages 2 years and older.

"We made the important decision to not wait for Part A to be completed before we reached out to the FDA for Type C feedback on our next steps toward the pivotal study, an interaction which we had originally estimated would be mid-year 2023. This earlier feedback enabled the acceleration into the Part B clinical trial of nomacopan in pediatric HSCT-TMA," said Rachelle Jacques, President and CEO of Akari. "Our decision to initiate a new pipeline program to develop nomacopan as a potential treatment for adults with HSCT-TMA was also an important one and will support our pediatric program. The significant unmet need is shared among both children and adults with dismal outcomes and no approved treatment options."

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 across both adult and pediatric patients who develop severe transplant-related TMAs is 80%.[1] Currently, there are no approved treatment options for adult or pediatric patients in the U.S. or Europe. Of the approximate 22,000 HSCTs that occur annually in the U.S., it is estimated that 8,400 of these lead to TMAs.[2-4] Approximately 3,400 are moderate to severe, complement-mediated TMAs and about 200 to 300 of these patients are children. The adult HSCT-TMA population is >10 times the size of the pediatric population.[2-4]

“Because the youngest age cohort is six months to two years, it is a very small group of patients and quite challenging to recruit into the study. With no approved treatment options and high mortality rates in this condition, it is important that we urgently move forward into the pivotal Part B clinical trial of nomacopan in the older age cohorts of pediatric HSCT-TMA patients,” said John Neylan, M.D., Executive Vice President and Chief Medical Officer of Akari. “We don’t want to leave any family behind, and we intend to keep Part A open so we may continue our efforts to enroll the youngest HSCT-TMA patients in this study.”

Because Part A is continuing, Akari is reporting that the Part A PK/PD data to date is sufficient to move into Part B with the older pediatric age cohorts and a full readout will be provided upon completion of the Part A study of nomacopan in pediatric HSCT-TMA.

In 2022, Akari was granted the Rare Pediatric Disease Designation for nomacopan in the treatment of pediatric HSCT-TMA. The Rare Pediatric Disease Designation is an important addition to the Orphan Drug and Fast Track designations previously granted by the FDA for nomacopan in pediatric HSCT-TMA.

References

1. Rosenthal J. Hematopoietic cell transplantation-associated thrombotic microangiopathy: a review of pathophysiology, diagnosis, and treatment. J BloodMed. 2016;7:181-186. Published 2016 Sep 2. doi:10.2147/JBM.S102235
2. Health Resources and Services Administration (HRSA), 2020
3. Jodele S, et al. Diagnostic and risk criteria for HSCT-associated thrombotic microangiopathy: a study in children and young adults. Blood. 2014;124(4):645-653.
4. Jodele S, et al. Complement blockade for TA-TMA: lessons learned from a large pediatric cohort treated with eculizumab. Blood. 2020;135(13):1049-1057.

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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