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

May 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): ☐

CONTENTS

On May 10, 2022, Akari Therapeutics, Plc (the "Company") issued a press release announcing the publication of phase II data of investigational nomacopan for the treatment of bullous pemphigoid (BP) in JAMA dermatology.

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

The information in paragraphs three to six 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.

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: May 11, 2022

Exhibit 99.1

Akari Therapeutics Announces Publication of Phase II Data of Investigational Nomacopan for the Treatment of Bullous Pemphigoid (BP) in JAMA Dermatology

- Patients received subcutaneous nomacopan (30 mg once daily) with lesional mometasone from Day 1 to 21 of treatment and nomacopan only from Day 21 to Day 42
- Seven of nine patients responded to nomacopan with three, regarded as complete responders, showing >80% reduction in BPDAI (BP disease activity index) activity and four patients showing >70% reduction in pruritis by day 42; two of nine patients were non-responders
- None of the nine patients reported Common Terminology Criteria for Adverse Events (CTCAE) grade three, four or five treatment-related adverse events

NEW YORK and LONDON, May 10, 2022 (GLOBE NEWSWIRE) – Akari Therapeutics, plc (Nasdaq: AKTX), a late-stage biotechnology company focused on development of advanced therapies for autoimmune and inflammatory diseases, announced positive results from the Phase II study of investigational nomacopan in bullous pemphigoid (BP) were published online in the Journal of the American Medical Association (JAMA) Dermatology. https://jamanetwork.com/journals/jamadermatology/article-abstract/2791461

“These positive Phase II data advanced our understanding of the nomacopan safety profile and informed duration of treatment in the ARREST-BP Phase III clinical trial, which is open for enrollment now,” said Rachelle Jacques, President and CEO of Akari Therapeutics.

BP is the most common autoimmune blistering skin disease. It typically affects people over the age of 65.[1] There are no approved therapies but superpotent topical steroids and high dose oral corticosteroids (OCS) are the current standard of care. The mortality rate in BP is ~three-fold higher than the general population due to the disease itself, and infections and cardiovascular conditions that are more common in older patients and are exacerbated by treatment with high dose OCS.[2] There is significant unmet need for an effective steroid-sparing therapy.

The goal of the Phase II study was to examine the safety and therapeutic potential of bispecific recombinant nomacopan, an inhibitor of both leukotriene B4 (LTB4) and complement C5, in patients with BP. The Phase II trial was a multicenter, single-group, nonrandomized controlled study conducted in the dermatology departments of hospitals in the Netherlands and Germany. Participants were enrolled between September 2018 and April 2020. Adult patients (aged >18 years) with mild to moderate, new-onset or relapsing BP were recruited into the study. Patients received nomacopan, 90 mg, subcutaneously on day one and 30 mg subcutaneously once daily until day 42.

The primary end point was the proportion of patients with Common Terminology Criteria for Adverse Events (CTCAE) grade three (severe AE), grade four (life-threatening or disabling AE), and grade five (death related to AE) adverse events associated, or possibly associated with nomacopan. Secondary end points included mean absolute and percentage changes in the Bullous Pemphigoid Disease Area Index (BPDAI) activity score, the BPDAI pruritus score, and the patient-reported outcome measures Dermatology Life Quality Index (DLQI) and Treatment of Autoimmune Bullous Disease Quality of Life (TABQOL). The BPDAI activity score provides an objective measure of disease extent by assessing blisters and urticarial/erythematous lesions affecting particular regions of the body surface and mucous membranes.[3]

A total of nine BP patients with a median age of 75 and a range of 55-85 years were included in the trial. There were no serious adverse events or CTCAE grade 3, 4 or 5 associated or possibly associated with nomacopan during the trial. The mean (90% CI) BPDAI activity score decreased from 32.0 (8.7) points on day one to 19.6 (9.0) points on day 42. Seven of nine patients (77.8%) responded to nomacopan with a reduction in the BPDAI activity score of at least eight points between day one and 42; where the minimum clinically important difference (MCID) in BPDAI activity is four.[4] In three responders, the reduction in BPDAI was 80% or greater. On day 42, the mean (90% CI) BPDAI pruritus score had decreased by 6.8 (4.6) points from 17.6 (4.0) points on day one. The mean (90% CI) DLQI score decreased from 11.3 (4.2) points at baseline to 6.4 (3.8) points by day 42, and the mean (90% CI) TABQOL score decreased from 14.6 (5.4) points at baseline to 10.3 (5.0) points on day 42.

References:

1. IPPF – International Pemphigus & Pemphigoid Foundation – Pemphigoid page. https://www.pemphigus.org/pemphigoid/. Accessed May 6, 2022

2. Tedbirt B, Gillibert A, Andrieu E, Hébert V, Bastos S, Korman NJ, Tang MBY, Li J, Borradori L, Cortés B, Kim SC, Gual A, Xiao T, Wieland CN, Fairley JA, Ezzedine K, Joly P. Mixed Individual-Aggregate Data on All-Cause Mortality in Bullous Pemphigoid: A Meta-analysis. JAMA Dermatol. 2021 Apr 1;157(4):421-430. doi: 10.1001/jamadermatol.2020.5598. PMID: 33729430; PMCID: PMC7970384

3. Murrell DF, Daniel BS, Joly P, et al. Definitions and outcome measures for bullous pemphigoid: recommendations by an international panel of experts. J Am Acad Dermatol. 2012;66(3):479-485. doi:10.1016/j.jaad.2011.06.032

4. Wijayanti A, Zhao CY, Boettiger D, Chiang YZ, Ishii N, Hashimoto T, Murrell DF. The Reliability, Validity and Responsiveness of Two Disease Scores (BPDAI and ABSIS) for Bullous Pemphigoid: Which One to Use? Acta Derm Venereol. 2017 Jan 4;97(1):24-31. doi: 10.2340/00015555-2473. PMID: 27244117

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 departure of our former Chief Executive Officers and other executive officers; 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.

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