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

April 2021

Commission file number: 001-36288

<u>Akari Therapeutics, Plc</u>

(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 April 28, 2021, Akari Therapeutics, Plc (the "Company") issued a press release announcing the Receipt of Fast Track Designation by the FDA for Nomacopan for the Treatment of Bullous Pemphigoid.

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

The information in paragraph one 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 April 28, 2021

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.

<u>Akari Therapeutics, Plc</u> (Registrant)

By: /s/ Clive Richardson Name: Clive Richardson

Chief Executive Officer and Chief Operating Officer

Date: April 28, 2021

Akari Therapeutics Receives FDA Fast Track Designation for Nomacopan for the Treatment of Bullous Pemphigoid

- A multicenter Phase III study of nomacopan for the treatment of moderate and severe bullous pemphigoid (BP) has been initiated
- Nomacopan has potential to replace long term steroid treatment (standard of care) in BP, which has multiple adverse effects and increases mortality in this elderly and frail population
- Recently announced U.S. Food and Drug Administration (FDA) approval of the Investigational New Drug Application (IND) enables clinical sites to be opened in the U.S. Clinical sites are planned to open in Europe mid-2021

NEW YORK and LONDON, April 28, 2021 – Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement and leukotriene systems are implicated, today announced that the FDA has granted Fast Track designation to nomacopan for the treatment of patients with moderate and severe BP. Nomacopan has also been granted orphan drug designation for nomacopan for the treatment of BP by the FDA and the European Medicines Agency (EMA).

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. A drug that receives Fast Track designation benefits from more frequent communications and meetings with the FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval.

Success in BP could potentially open up a range of other severe dermatological conditions for treatment with nomacopan where C5 and LTB4 are implicated, including hidradenitis suppurativa, epidermolysis bullosa acquisita and mucous membrane pemphigoid.

About Bullous Pemphigoid (BP)

BP is a severe orphan autoimmune inflammatory blistering skin disease with no approved treatments in the U.S. and Europe. This disease of the elderly is primarily treated with steroids and immunosuppressants for six months or more which bring with them deleterious side effects and an approximately three-fold increase in mortality in the BP treated population. The prevalence of BP is estimated to be approximately 120,000 patients in U.S. and EU5 with moderate and severe patients making up around three-quarters of the patient population. In BP patients there is evidence that both terminal complement activation (via complement component C5) and the lipid mediator leukotriene B4 (LTB4) have a central role in driving the disease.

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 binds to and inhibits leukotriene B4 (LTB4) activity.

Cautionary Note Regarding Forward-Looking Statements

Certain 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 therefrom; 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.

For more information

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