
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

February 2021

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 February 25, 2021, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that the Company presents new preclinical data highlighting the potential of long-acting PASylated nomacopan to treat retinal diseases, including age-related macular degeneration (AMD) and uveitis.

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

The information in paragraphs one and two 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 February 25, 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.

Akari Therapeutics, Plc
(Registrant)

By: /s/ Clive Richardson
Name: Clive Richardson
Chief Executive Officer and Chief Operating Officer

Date: February 25, 2021

Akari Therapeutics Presents New Preclinical Data Highlighting Potential of Long-Acting PASylated Nomacopan to Treat Retinal Diseases, Including Age-Related Macular Degeneration (AMD) and Uveitis

- *A newly published review article in the journal CELLS highlights the role LTB4 plays in the induction of vascular endothelial growth factor (VEGF) damage and retinal inflammation in the eye.*
- *Elevated VEGF is associated with choroidal neovascularisation (CNV), the cause of wet AMD. Recent data from a laser-induced CNV model suggests one dose of long-acting PASylated nomacopan (PASnomacopan) reduced neo-vascularisation by the same amount as Eyelea®, a U.S. Food and Drug Administration (FDA)-approved treatment for AMD.*
- *The combined impact of bifunctional nomacopan, which inhibits LTB4, and thereby VEGF production, and also inhibits complement C5, may provide a unique modality for treatment of a number of serious eye diseases, including uveitis and both dry and wet AMD.*

NEW YORK and LONDON, February 25, 2021 - Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where complement (C5) and/or leukotriene (LTB4) systems are implicated, announced today the publication of new data in the journal CELLS. The paper, entitled "Immune-Mediated Retinal Vasculitis in Posterior Uveitis and Experimental Models: The Leukotriene (LT)B4-VEGF Axis," highlights the importance of the LTB4-VEGF axis in the development of sight-threatening retinal inflammation. In a non-infectious allergic uveitis animal model, PAS-nomacopan reduced VEGF by more than 50% compared to saline control, equivalent to the inhibition caused by an anti-VEGF antibody. In addition, PAS-nomacopan was significantly more effective in reducing retinal inflammation than the anti-VEGF antibody.

Separately, Akari recently completed a preclinical study in an industry standard model of laser-induced CNV in which intravitreally injected PAS-nomacopan was compared to Eyelea®, an FDA-approved treatment for wet AMD. In this model, PAS-nomacopan injected once during the 16-day treatment period was equivalent to Eyelea® in reducing neo-vascularisation.

Further pharmacokinetic and pharmacodynamic work is underway with PAS-nomacopan to define the optimal dose interval that could be used in clinical trials. PAS-nomacopan is an engineered version of nomacopan with an extended half-life [Kuhn et al, 2016] to increase residency time, thereby reducing injection intervals into the eye. Virginia Calder, Ph.D., Professor of Ocular Immunology at the University College London Institute of Ophthalmology said, "Nomacopan has shown a promising reduction in disease severity in a pre-clinical uveitis model and therefore has the potential to provide a new therapeutic approach in difficult to treat retinal eye diseases such as uveitis where LTB4, VEGF and complement activation are believed to drive disease pathology."

The work by Professor Calder and colleagues taken together with the CNV results suggest that long-acting PAS-nomacopan could have important applications in a wide range of sight threatening back of the eye diseases for which there are currently limited treatment alternatives. Akari is currently exploring multiple partnering options for both its surface of the eye program treated with topical nomacopan and with PAS-nomacopan for the back of the eye program.

Overview of Potential Target Diseases

Non-infectious posterior uveitis (NIU) is a major cause of vision loss in young and middle-aged people in the U.S. and Europe accounting for 10 -15% of blindness in this population. The only approved products for treatment of NIU are corticosteroids, tumour necrosis factor (TNF) blockers and immunosuppressants, but these all have serious treatment limiting side effects including glaucoma, cataracts and liver failure.

In wet AMD, growth of new blood vessels in the retina, known as choroidal neovascularisation (CNV), together with leakage of proteins and blood components has been associated with vision loss. While VEGF antagonists such as aflibercept (Eylea®) and ranibizumab (Lucentis®), have become the mainstay of treatment of wet AMD, they do little to combat other types of retinal inflammation such as uveitis and dry AMD¹.

Dry AMD also named geographic atrophy (GA) is a more common condition for which there is currently no approved treatment. Because of its association with complement degradation products there has been interest in complement inhibition as a treatment option. However, in clinical trials involving complement inhibitors, a reduction in the progression of GA was associated with the development of CNV in between 9% and 21% of patients^{2, 3}. Nomacopan which simultaneously reduces the complement drive of GA and reduces VEGF through its LTB4 inhibitory activity may potentially be an effective treatment option.

¹Nishi Gulati, et al. "Vascular endothelial growth factor inhibition in uveitis: a systematic review." British Journal of Ophthalmology. 2011.

²Glenn J. Jaffe, MD, et al. "C5 Inhibitor Avacincaptad Pegol for Geographic Atrophy Due to Age-Related Macular Degeneration: A Randomized Pivotal Phase 2/3 Trial." American Academy of Ophthalmology. August, 2020.

³David S. Liao, MD, et al. "Complement C3 Inhibitor Pegcetacoplan for Geographic Atrophy Secondary to Age-Related Macular Degeneration: A Randomized Phase 2 Trial." American Academy of Ophthalmology. July 16, 2019.

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 inhibits leukotriene B4 (LTB4) activity.

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. You should not place undue reliance upon the Company’s forward looking statements. Except as required by law, the Company undertakes no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this press release. 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; our ability to enter into collaborative, licensing, and other commercial relationships and on terms commercially reasonable to us; 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; risks associated with the SEC investigation; 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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