
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 2020

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 1, 2020, Akari Therapeutics Plc (the “Company”) issued a press release announcing positive topline results from its Phase II study of nomacopan in bullous pemphigoid patients. Further, on the same date, the Company uploaded to its website a power point presentation summarizing the topline results of the Phase II study of nomacopan. Copies of the press release and presentation are attached hereto as Exhibit 99.1 and 99.2, respectively, and incorporated herein by reference.

The information contained in the first paragraph and paragraphs four through eight of Exhibit 99.1 are 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 May 1, 2020
99.2	Presentation dated April 2020

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: May 1, 2020

Akari Therapeutics Announces Positive Topline Results from Fully Recruited Phase II Study of Nomacopan in Bullous Pemphigoid Patients

- Study achieved primary endpoint of no drug-related serious adverse events and main secondary efficacy endpoints with 7 of the 9 treated patients showing a rapid and clinically significant reduction in Bullous Pemphigoid Disease Area Index (BPDAI) score
- Nomacopan has potential to replace long term steroid treatment (standard of care), which has multiple adverse effects in this elderly and frail population
- Nomacopan granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of BP in September 2019
- Expect to meet with the FDA and the European Medicines Agency (EMA) to discuss pivotal trial design in third quarter 2020

NEW YORK and LONDON, May 1, 2020 – Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement and/or leukotriene systems are implicated, announces that it achieved the primary and secondary endpoints for nomacopan in its fully recruited Phase II trial in BP and is planning to discuss Phase III pivotal study designs with the FDA and EMA.

“The role of both the leukotriene and complement pathways has been well documented in BP and the rapid clinical response and good safety profile seen in this phase II study was extremely positive given nomacopan’s unique bi functional inhibition of both C5 and LTB₄,” commented Clive Richardson, Chief Executive Officer of Akari Therapeutics. “Our next steps are to work closely with U.S. and European regulators in order to secure a clear path forward to a pivotal trial for this severe orphan disease which has significant unmet clinical need and is a potential gateway to other dermatological conditions.” Christian Sadik, M.D., lead investigator from the Department of Dermatology, University of Lubeck, Germany, commented, “Clinicians continue to seek an effective treatment for BP that can be administered in outpatient settings and minimize the use of steroids, which often cause significant clinical complications in this at risk population. I am therefore delighted by the promising results of Akari’s Phase II trial in BP which shows rapid efficacy, similar to potent steroids, but with the advantage of being well tolerated, and possessing a good safety profile.”

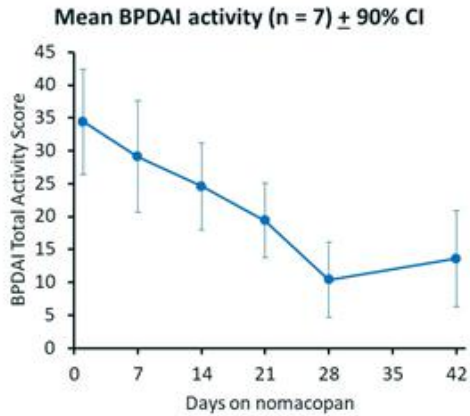
Summary of Topline Results of Phase II Study

The fully recruited Phase II trial of nomacopan for treatment of mild-to-moderate BP was a six-week open-label single-arm study evaluating safety and efficacy in 9 patients (7 with moderate severity, 2 mild). Patients entering the trial were at their choice permitted to use a low dose of mometasone¹ topically to lesions for up to Day 21 as this was the first study of nomacopan in BP patients.

The trial achieved the main efficacy endpoints, which were clinically significant improvements in the Bullous Pemphigoid Disease Area Index (BPDAI) which provides an objective measure of the area of skin affected by inflammatory skin lesions (blisters, erythema and urticaria). Seven out of 9 patients showed a decrease by 4 or more points (deemed a minimal clinically important difference²) in the BPDAI activity score between baseline (Day 1) and Day 42, while 2 patients, both with relapsing disease on admittance to the trial, were non responders. The graph below shows the mean BPDAI activity score over the period of the trial for the 7 of 9 responders with more than a 20 point fall over the 42 day study and a decline in the mean BPDAI index by 29% at day 14, 70% at day 28 and 61% by day 42.

In the graph of mean BPDAI activity for the 7 responding patients, one patient experienced a flare in their disease after day 28, which is common in BP where patients are typically treated for 6 months or more with steroids to enable disease control. The two non responders showed worsening disease with an increase in their BPDAI score. The combined mean decline in the BPDAI index for all 9 patients was approximately 40% at day 42.

Improvement in BPDAI Index



Note : Nomacopan dosing initiated Day 1. The BPDAI activity score used above is a composite objective measure of the area of skin affected by blisters/erosions, cutaneous urticaria/erythema, mucosal blisters/erosions.

Of the 7 responders, 3 showed an 80%+ reduction in BPDAI score and 3 an approximately 40% reduction in BPDAI score within six weeks of starting nomacopan. For the responders, the response on nomacopan was rapid and is similar to what is seen with patients treated on potent oral steroids which is standard of care in the U.S. and parts of Europe for moderate to severe patients. Similarly, under typical standard of care around 20% of BP patients are considered non-responders³.

Nomacopan, dosed daily by subcutaneous injection, was well tolerated in this frail BP patient population with multiple comorbidities. The primary endpoint was the proportion of participants reporting grade 3, 4 and 5 adverse events, which are related/possibly related to nomacopan. None of the 9 patients reported any grade 3, 4 and 5 treatment related adverse events. The safety profile in BP mirrors over 30 cumulative patient-years of data from patients treated with nomacopan across all conditions in clinical development where the drug has proven well tolerated with no drug-related serious adverse events have been observed to date.

A summary of the topline Phase II results of nomacopan for the treatment of BP is available under [Presentations](#) in the Investor Relations section of the Company's website at www.akarix.com. The Company expects to report full data from the Phase II study at the European Academy of Dermatology and Venereology (EADV) congress in October 2020.

1. Experts consider that mometasone may stabilize but not improve the symptoms of BP. Mometasone is a short acting, mid strength topical steroid not typically given as a treatment for BP
2. Wijayanti A, Zhao CY, Boettiger D et al. The Reliability, Validity and Responsiveness of Two Disease Scores (BPDAI and ABSIS) for Bullous Pemphigoid: Which One to Use? *Acta Derm Venereol.* 2017; 97:24-31
3. Roujeau J-C, Morel P, Dalle E, Guillot B et al. Plasma Exchange in Bullous Pemphigoid. *Lancet* 1984; 324:486-489

Background on 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, most common in 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 over 100,000 patients in U.S. and Europe.

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. Ex vivo data in BP patients, published in the August 2019 edition of JCI Insight [LINK], showed a pronounced accumulation of LTB4 and C5 and its activation products in the inflamed skin of BP patients. This underlies the rationale for treatment with nomacopan which is a unique bifunctional inhibitor of both C5 and LTB4 and a range of downstream cytokines.

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, is a C5 complement inhibitor that also independently and specifically inhibits leukotriene B4 (LTB4) activity. Nomacopan is being clinically evaluated in: bullous pemphigoid (BP), atopic keratoconjunctivitis (AKC), and thrombotic microangiopathy, or TMA. Akari believes that the dual action of nomacopan on both C5 and LTB4 may be beneficial in AKC and BP. Akari is also developing other tick derived proteins, including longer acting versions.

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 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 outbreak of coronavirus; risks related to material weaknesses in our internal controls over financial reporting and risks relating to the ineffectiveness of our disclosure controls and procedures; 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.

For more information

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Summary of Topline Phase II Results Nomacopan for Treatment of Bullous Pemphigoid

April 2020

DISCLAIMER

Certain statements in this presentation constitute contains “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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 impact of the outbreak of coronavirus; 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 on March 31, 2020.

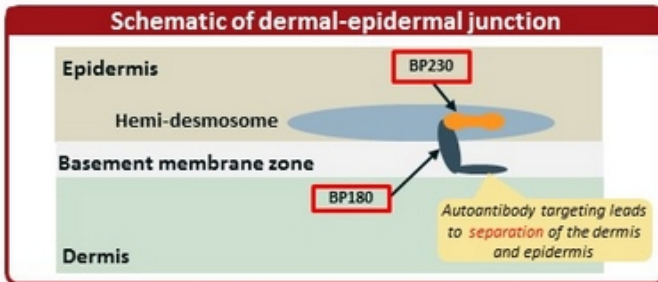
The statements made in this presentation speak only as of the date stated herein, and subsequent events and developments may cause our expectations and beliefs to change. Unless otherwise required by applicable securities laws, we do not intend, nor do we undertake any obligation, to update or revise any forward-looking statements contained in this presentation to reflect subsequent information, events, results or circumstances or otherwise. While we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

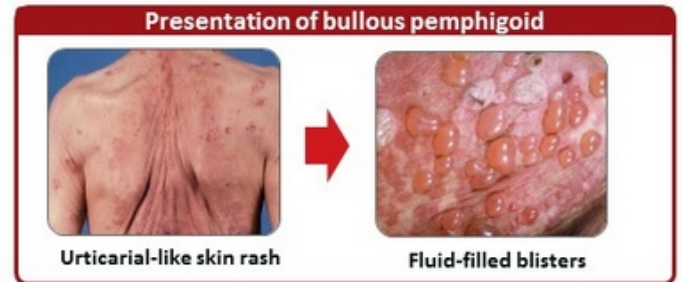
This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

Bullous Pemphigoid

Significant Unmet Need



Key molecular targets that lead to BP pathophysiology



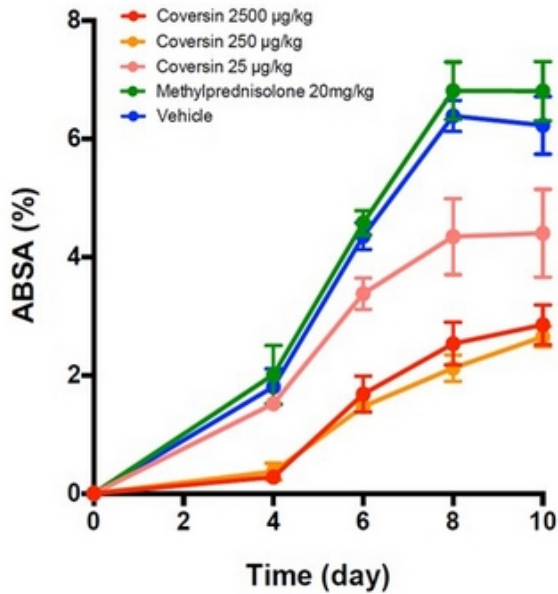
- Severe autoimmune blistering skin disorder primarily of the elderly, caused by immune complex mediated inflammation
- **No approved therapy. Current treatment with chronic corticosteroids poses substantial health concerns and 3 – 4-fold increase in mortality**
- **KOLs: essentially no change in standard of care in decades**
- Understanding of BP etiology has grown, but specific targeted therapies are lacking
- Evidence (pre-clinical and human tissue) that C5 and LTB4 have a beneficial and additive role in disease control*
- Orphan condition, with a prevalence of circa 120K patients in US and EU

* Preclinical studies with Nomacopan showed a dose response and combined C5 & LTB4 more effective than LTB4 alone: Sezin (2019) *JCI insight 4: e128239*. Akari also found elevated C5/LTB4 in an *ex-vivo* study with Lubeck University of BP patients

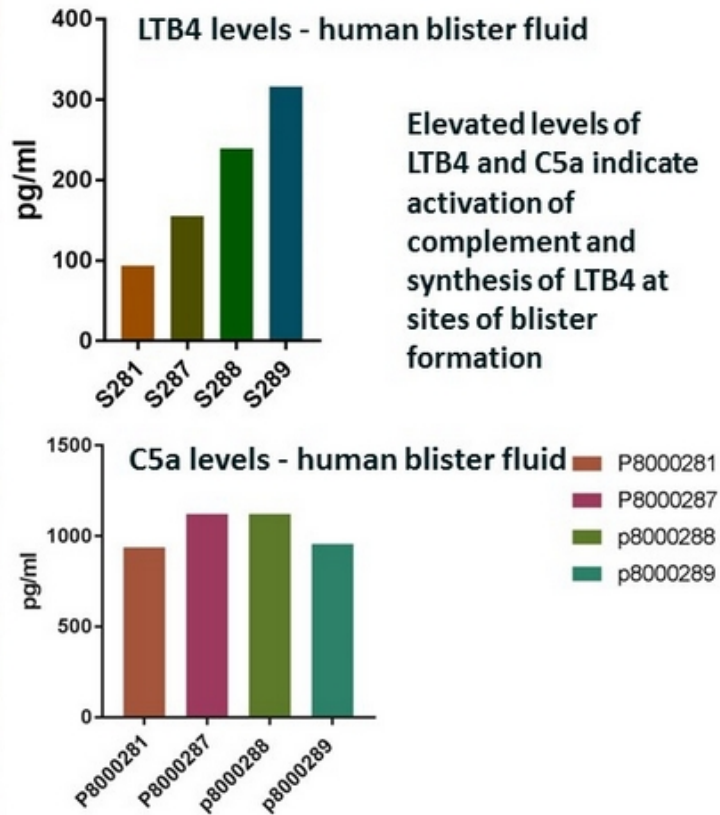
Rational for nomacopan in BP

Preclinical Efficacy and Elevated C5a/LTB4 (in Human)

Preclinical passive mouse model of epidermolysis bullosa acquisita (EBA) from Dr. Sadik in Lubeck, Germany; leading Bullous Pemphigoid center



- Clear dose response
- ~60% reduction in affected area on nomacopan (SC) compared to vehicle or steroid
- P=0.002 between vehicle and 250 µg/kg





Phase II Study nomacopan in Bullous Pemphigoid

Bullous Pemphigoid Phase II Study Patients with Mild-to-Moderate Disease

Trial approved in Netherlands (2 sites) and Germany (6 sites)

Study design <ul style="list-style-type: none">• Phase II Single arm (n = 9); 42 days treatment• Active bullous pemphigoid; newly diagnosed or recurrent	
Treatment <ul style="list-style-type: none">• Nomacopan SQ dosing• <u>Day 1</u>: 60 mg and 30 mg 12 hours later, <u>Day 2-42</u>: 30 mg once daily	
Primary endpoint Safety	Secondary endpoints Efficacy evaluated by BPDAl (BP disease activity index) and QoL at day 42

- Day 1 to 21: nomacopan (30 mg once daily) + lesional mometasone only
- Day 21 to 42: nomacopan only
- Any use of mometasone or any other steroid after Day 21 considered rescue therapy

Summary of Fully Recruited Phase II BP Data

Patient Demographics

- 7 moderate and 2 mild BP patients; 5 female, 4 male; median age 75; median weight 89.4kg; median BMI 30.2
- Median Karnofsky score 80 (range 60 – 90)
- 5 patients newly presenting BP and 4 relapsing disease
- Typical comorbidities and concomitant medications of an elderly patient population

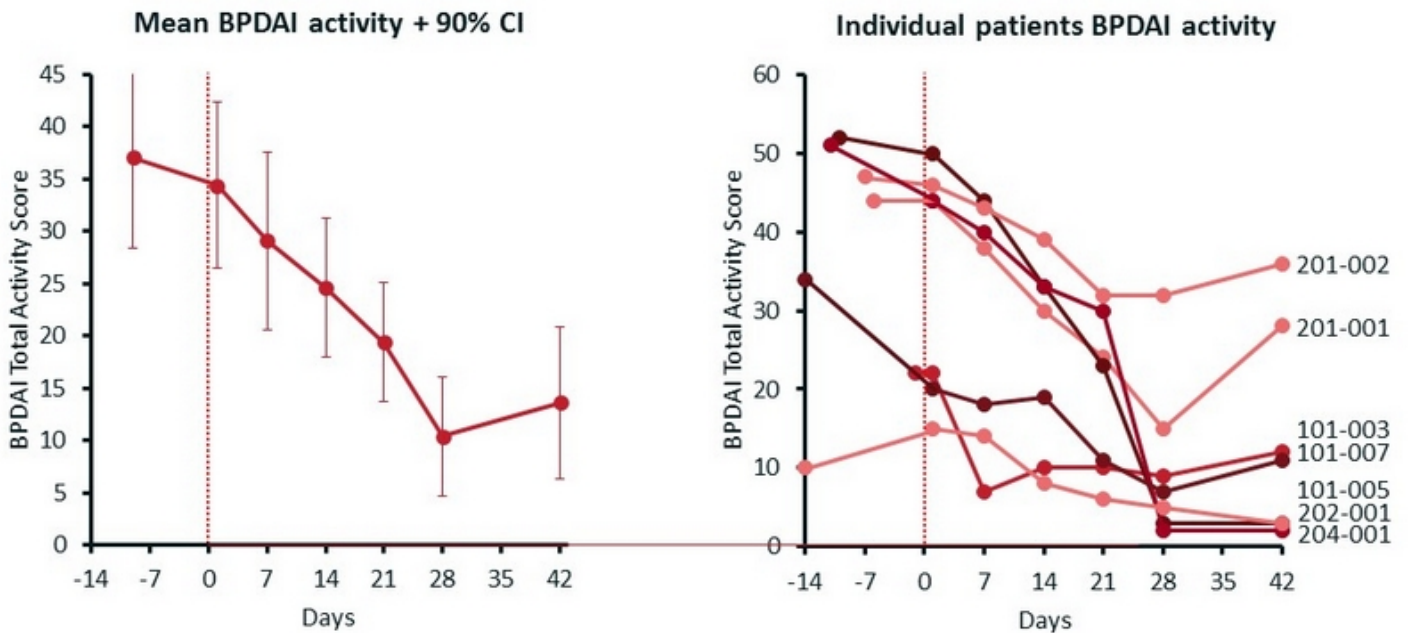
Patient Safety

- No deaths
- None of 9 patients reported grade 3, 4 or 5 treatment-related adverse events

Efficacy

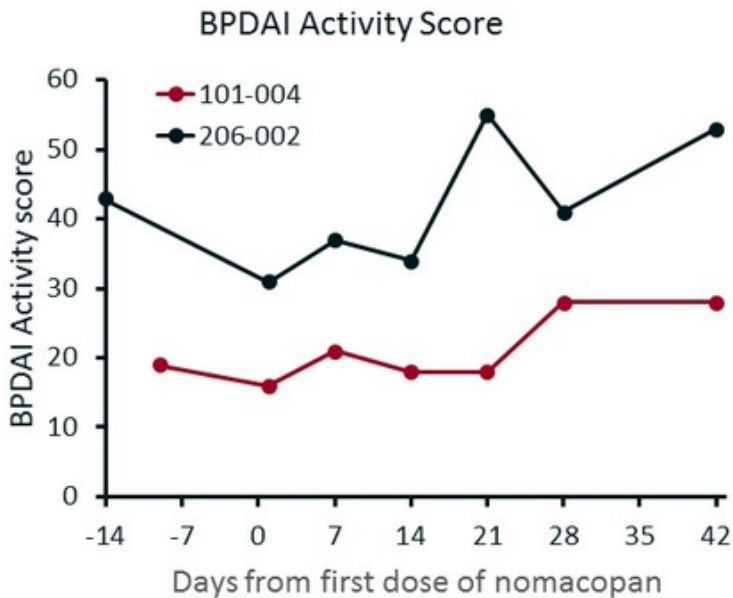
- 7 of 9 patients responded to nomacopan - with 3 showing > 80% reduction in BPDAl activity & 4 showing > 70% reduction in pruritis by Day 42
- 2 of 9 patients were non-responders

Patient BPDAI Activity Scores (n=7) Excluding Two Non-Responders



- Prior treatment withdrawn approximately one week prior to treatment with nomacopan
- Lesional mometasone permitted until Day 21. Mometasone is a moderate topical steroid that was given at a low dose which can help to stabilise BP but is not used to control BP

Patient BPDAI Activity Scores Two Non-Responders

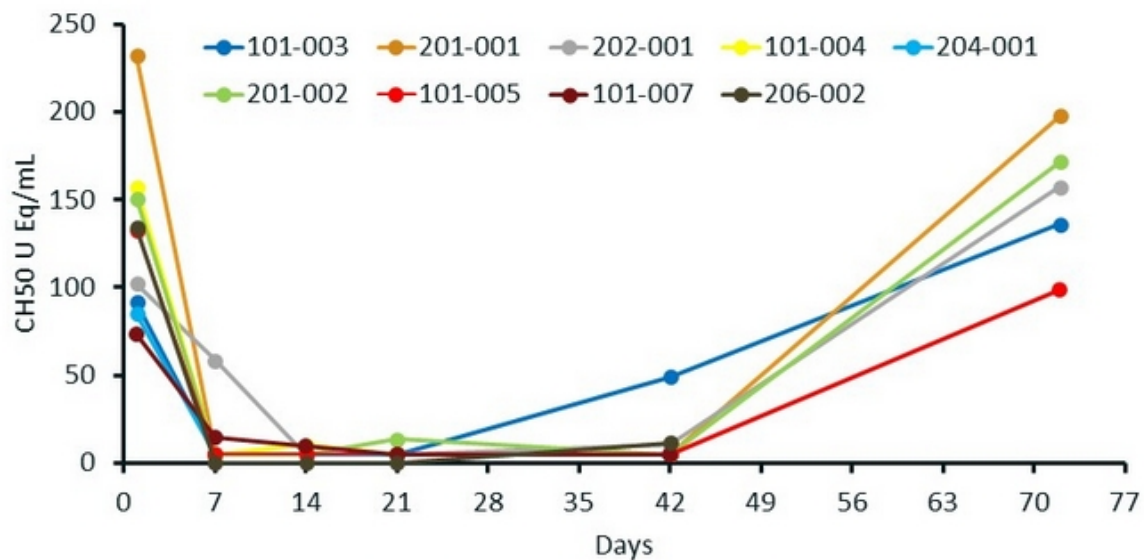


- Both non-responders had long term relapsing disease on admittance
- Combined decline in mean BPDAI activity score at day 42 for all nine patients including non responders was circa 40% at Day 42
- Patient 101-004 received rescue therapy with betamethasone at Day 28 of nomacopan dosing which was ineffective so initiated oral prednisone on Day 39 and topical clobetasol on Day 43. Both super potent steroids were still being used at follow up (Day 72)
- Patient 206-002 received prednisone at Day 62

Concomitant Treatments

- Patients on BP typically are referred to a hospital and, as such, may be on treatment prior to dosing. Oral steroid treatments were an exclusion from the Phase II study
 - 5 out of 9 patients on treatment prior to nomacopan dosing
 - 3 were on topical clobetasol (a relatively strong topical steroid) which was stopped 2 to 7 days prior to treatment with nomacopan to avoid residual effects
 - None on oral steroids
- Mometasone provided topically to lesions for up to day 21 as this was the first study of nomacopan in BP patient
 - Experts consider that mometasone may stabilize but not improve BP symptoms
 - Mometasone is a short-acting, mid-strength topical steroid not typically given as a treatment for BP

Terminal Complement Activity - BP Patients



- Ablating dose Day 1: 60mg and 30 mg 12 hours later
- Maintenance dose: 30mg once daily until Day 42

Notes:

- a) Data to Day 42 for all 9 subjects and follow up data at Day 72 for 5 patients
- b) 202-001 did not receive a full ablating dose (60mg total on Day 1 rather than 90mg)
- c) 101-003 had low (near normal) total C5 on Day 42 suggesting that the patient may recently have missed one or more doses of nomacopan

Key Phase II Conclusions


Primary Observations

- 1) Rapid clinical response on nomacopan
- 2) Quantum of response similar to potent oral steroids
- 3) Indications that remission may be achievable with 6 weeks of treatment
- 4) Supports a Phase III design of rapid steroid tapering
- 5) Good safety profile and well tolerated

Unknowns

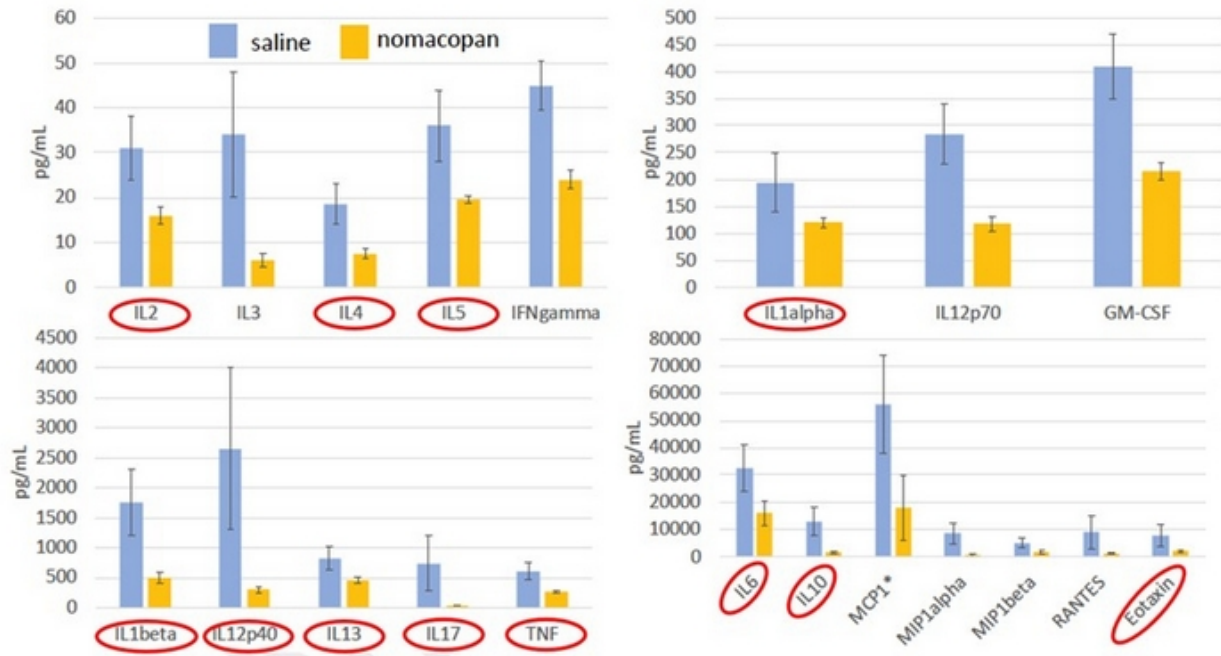
- 1) Longer term remission rates
- 2) Additive effect of nomacopan and oral steroids

Therapeutic Approaches to BP

- Major unmet medical need of the elderly in aging patient population
 - No approved therapy for BP and no new treatment in last 40 years
 - BP treated with steroids increases risk of mortality compared to age-matched controls by ~3-4X; causes hospitalization/clinical and home nurse home care
 - Several drugs have been tested in trials for BP, and are believed to not have subsequently progressed into further development:
 - Novartis – ligelizumab - anti Ig E
 - GSK - mepolizumab - IL5 inhibition
 - Bertilimumab - Eotaxin-1 antibody
 - Eli Lilly - Taltz - Anti-IL17a mAb
 - Rituximab : targets CD20
 - Few other known biological drugs currently in development
 - Dupilumab – IL4 and IL13 inhibition
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Nomacopan Inhibits Downstream Cytokine & Chemokine Signalling Cascades Implicated in BP Pathology

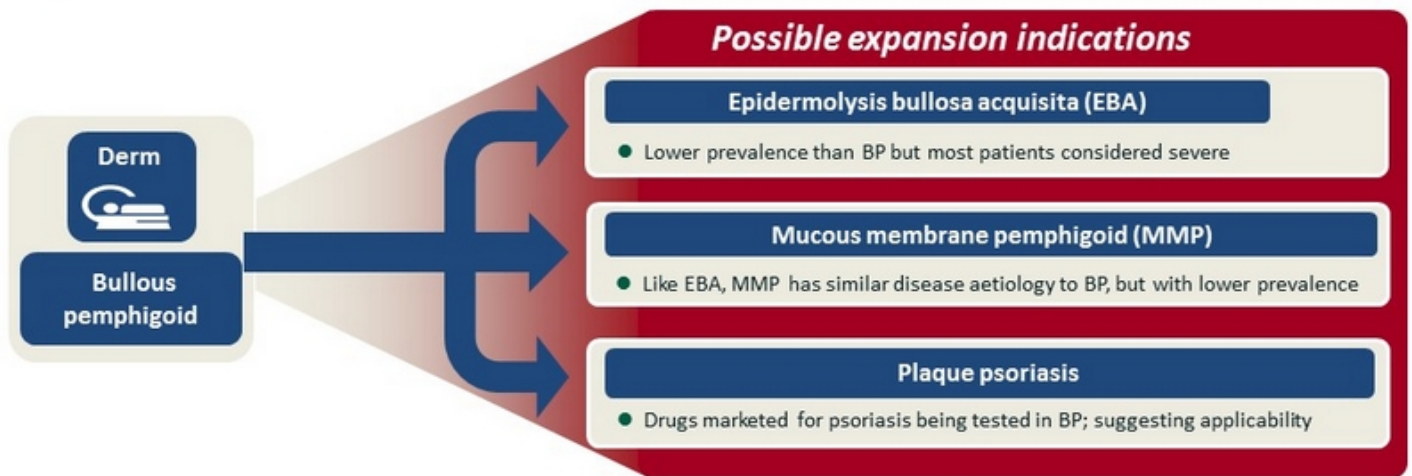
Inflammatory markers significantly inhibited by nomacopan in mouse model of polymicrobial sepsis. Cytokines/chemokines circled in red have been associated with BP



Data adapted from: Figures 1, 2 and 3 of Huber-Lang et al, *J Immunol.* 2014; 192: 5324 – 5331

Notes: *value shown for MCP1 is scaled to 10-fold less than measured value to allow use of same y-axis scale; chemokines are MCP1 (CCL2); MIP1alpha (CCL3); MCP1beta (CCL4); RANTES (CCL5) and eotaxin-1 (CCL11)

BP: Gateway to Other Indications



- Other autoimmune blistering skin diseases are categorized by auto-antibodies to either structural epidermal proteins or dermal-epidermal junction proteins
- Symptoms follow that of BP and are generally moderate to severe
- Generally, physicians treating BP will also treat other AIBDs such that approval in BP may drive physician interest in nomacopan for other diseases

Source: LEK 2018 Report



Summary of Topline Phase II Results Nomacopan for Treatment of Bullous Pemphigoid

April 2020