# FACTSHEET

November 2017

**Akari Therapeutics** is a clinical-stage biopharmaceutical company creating drugs for acute and chronic orphan inflammatory diseases by modulating one or both of the complement C5 and leukotriene pathways.

- Lead drug candidate, Coversin™, anticipated to start Phase III clinical trial in PNH in Q1 2018
- Coversin administered subcutaneously compared with currently approved eculizumab (Alexion Pharmaceuticals; Soliris®) which is administered IV
- No drug-related SAEs reported, to date, in Coversin clinical trials
- Coversin has potential in the treatment of multiple indications

## CLINICAL INDICATIONS

**Akari's two lead indications are complement-focused, anti-inflammatory programs addressing PNH and aHUS. Soliris® is currently the only drug approved for these indications. It had net product sales of ~$2.8 billion in 2016 with an annual cost of treatment in the U.S. of ~$500,000**

### Paroxysmal Nocturnal Hemoglobinuria (PNH)

PNH is an ultra-rare, life-threatening and debilitating disease of the blood PNH which affects 1-1.5 persons per million of the population. Due to an acquired genetic deficiency, the patient's own blood cells are unprotected against background complement activity which then causes uncontrolled haemolysis, leading to life-threatening complications. **PHASE II TRIAL ANTICIPATED TO START Q1 2018**

### Atypical Hemolytic Uremic Syndrome (aHUS)

Complement-mediated 'atypical' hemolytic uremic syndrome (aHUS) is a chronic and life-threatening ultra-rare genetic disease with an estimated prevalence of seven per one million individuals in which uncontrolled complement activation causes blood clots in small blood vessels throughout the body, known as thrombotic microangiopathy (TMA), leading to kidney failure, stroke, heart attack and death. Efficacy of C5 inhibition in aHUS has been demonstrated by the approval of eculizumab for this indication. aHUS physicians have expressed support for once-daily Coversin. **PHASE II TRIAL ANTICIPATED TO START Q4 2017**

**Akari is developing drugs for a number of orphan diseases where dual control of the complement C5 and leukotriene B4 pathways is believed to be essential for treatment. This is possible because Coversin has two independent binding sites: one for C5 and one for LTB4**

### Atopic Keratoconjunctivitis (AKC)

AKC is a severe inflammation of the surface of the eye caused by the infiltration of immune cells such as neutrophils and T cells which can lead to blindness. Topical drugs, such as steroids or cyclosporin, are often not effective or cannot be given chronically. Both the complement and LTB4 pathways are thought to be involved in the onset of the condition. **PHASE II TRIAL ANTICIPATED TO START IN H1 2018**

### Bullous Pemphigoid (BP)

BP is a rare skin condition that causes large, fluid-filled blisters and occurs when your immune system attacks a thin layer of tissue below the outer layer of skin. Both the complement and LTB4 pathways are thought to be involved in the onset of the condition. **PHASE II TRIAL ANTICIPATED TO START IN H1 2018**


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## MANAGEMENT TEAM

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*Chief Executive Officer*

**Mr. Clive Richardson**
*Chief Operations Officer*

**Mr. Robert M. Shaw**
*Chief Legal & Compliance Officer, Company Secretary*

**Mr. Dov Elefant**
*Chief Financial Officer*

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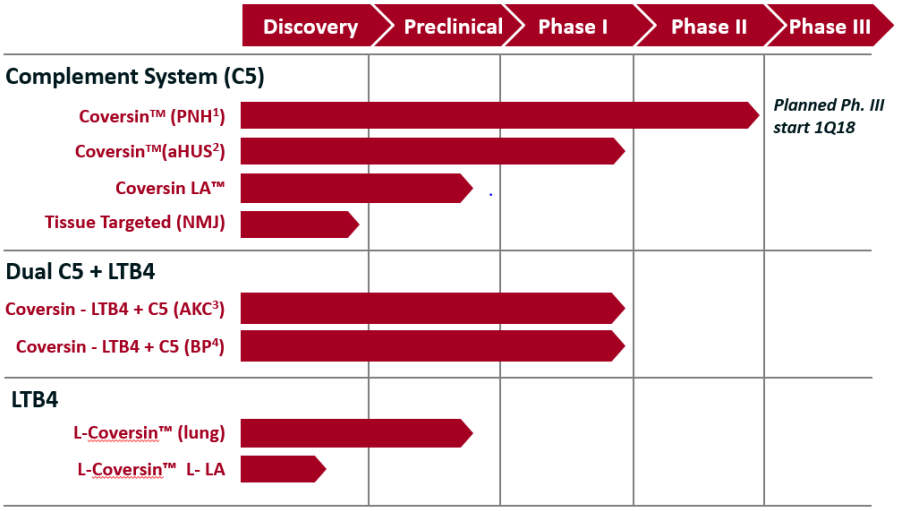
# DEVELOPMENT PIPELINE




*1. PNH: Paroxysmal nocturnal hemoglobinuria; 2. aHUS: Atypical hemolytic-uremic syndrome;*
*3. AKC: Atopic keratoconjunctivitis; 4. BP: Bullous Pemphigoid*



# DIFFERENTIATORS

- Coversin, Akari's lead drug candidate, has an insulin-like **subQ delivery formulation** for PNH and aHUS versus IV for Soliris®, potentially giving patients the ability to self-inject and have more control over their condition
- Like Soliris, Coversin binds to C5 but **at a different site.** Akari has demonstrated in a Ph II trial, which has enrolled one patient to date, that Coversin can be efficacious in the treatment of an eculizumab-resistant patient. This patient has been on Coversin for ~22 months
- Akari is exploring **multiple routes of administration** – subQ, topical and inhaled
- **Dual binding sites** on Coversin (C5 + LTB4) have the potential to treat a wide range of inflammatory diseases where both pathways are implicated (complement and leukotrine)
- Akari is currently developing a second generation **long-acting version** of Coversin which has the potential for weekly subQ dosing
- One pipeline drug, L-Coversin™, targets LTB4 which is implicated in several inflammatory conditions (e.g. Alpha-1 Antitrypsin Deficiency (AATD) in the lung and in cancer)

# THE SCIENCE

Coversin is a recombinant small protein (16,740 Da) derived from a native protein discovered in the saliva of the *Ornithodoros moubata* tick, where it modulates the host immune system to allow the parasite to feed without alerting the host to its presence or provoking an immune response.

## Recent News:

**Oct. 18, 2017:** Akari Therapeutics Announces Pricing of Public Offering of ADRs
**Oct. 11, 2017:** Akari Therapeutics Announces Further Clinical Progress
**Sept. 21, 2017:** Akari Therapeutics Announces Regulatory Progress Following FDA Meeting
**Aug. 21, 2017:** Akari Therapeutics Announces Appointment of David Horn Solomon as CEO