

PRESS RELEASE

Number 21

WACKER's ESETEC® Technology Achieves a 12-Fold Higher Yield in the Manufacture of Akari's Investigational Nomacopan

Jena, May 16, 2022 – The new ESETEC® technology generation developed by WACKER has significantly increased the yield of investigational nomacopan from Akari Therapeutics 12-fold. Nomacopan is the lead asset of Akari. The company develops advanced therapies for autoimmune and inflammatory diseases.

As contract manufacturer, Wacker Biotech, a subsidiary of the WACKER Group, has developed and optimized a production process for nomacopan using the patented ESETEC® technology. Various ESETEC® strains have already been used for manufacturing the protein. "By continually investing in the ESETEC® technology, we have been able to increase the yield of investigational nomacopan significantly by a factor of twelve," says Guido Seidel, Managing Director of Wacker Biotech GmbH and responsible for the biopharmaceuticals business at WACKER. "In addition, comparative studies have shown that the quality of the proteins remained consistently high after the switchover to new strains. This demonstrates the effectiveness and excellence of our ESETEC® system."

The ESETEC® expression technology is based on modified *E. coli* strains, which is designed to secrete the desired pharmaceutical proteins into the culture broth in the correctly folded conformation

during fermentation. This process can be aided by additional overexpression of proprietary folding helpers. Thus, with ESETEC[®], even complex molecules can be produced in high yields and secreted into the culture medium in active form. The efficiency of the secretion depends largely on the properties of the respective target protein. While some proteins are easily secreted into the culture medium, some others remain trapped in the periplasm of the *E. coli* bacteria. Wacker Biotech has modified the secretion system to solve this problem. The latest generation of the ESETEC[®] system now allows proteins to be expressed into the culture medium at a controlled rate. This maximizes the folding and secretion efficiency and yields can be significantly increased. ESETEC[®] thus enables the production of even complex proteins in high quality and with high yields. The technology helps to reduce the manufacturing costs of innovative drugs.

About Wacker Biotech

Wacker Biotech GmbH, Wacker Biotech B.V. and Wacker Biotech US Inc. are full-service contract manufacturers of therapeutic proteins, live microbial products (LMPs), vaccines based on microbial systems, and of plasmid DNA. Wacker Biotech's portfolio extends from strain/process development and analytical testing through to production for clinical and commercial applications. Wacker Biotech maintains three GMP-compliant (Good Manufacturing Practice), FDA- and EMA-certified production plants at its Jena and Halle sites in Germany and in Amsterdam in the Netherlands. The company's most recent acquisition is its San Diego site (Wacker Biotech US Inc.), added in February 2021. Wacker Biotech GmbH, Wacker Biotech B.V. and Wacker Biotech US Inc. are wholly-owned subsidiaries of the Munich-based WACKER Group. For more information, visit:

www.wacker.com/biologics

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, please visit www.akaritx.com






The production facility at Wacker Biotech GmbH in Jena: pharmaceutical proteins are produced in fermenters with the help of modified *E. coli* bacteria. (Photo: WACKER)

Note:

This photo is available for download at: <http://www.wacker.com/pressreleases>

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The company in brief:

WACKER is a globally active chemical company with some 14,400 employees and annual sales of around €6.21 billion (2021). WACKER has a global network of 26 production sites, 23 technical competence centers and 52 sales offices.

WACKER SILICONES

Silicone fluids, emulsions, rubber grades and resins; silanes; pyrogenic silicas; thermoplastic silicone elastomers

WACKER POLYMERS

Polyvinyl acetates and vinyl acetate copolymers and terpolymers in the form of dispersible polymer powders, dispersions, solid resins and solutions

WACKER BIOSOLUTIONS

Biotech products such as cyclodextrins, cysteine and biologics, as well as fine chemicals and PVAc solid resins

WACKER POLYSILICON

Polysilicon for the semiconductor and photovoltaic industries