



## **Akari Therapeutics Initiates GMP Manufacturing of AKTX-101 ADC Program to Support Phase 1 First-in-Human Clinical Trial**

*Akari Will Exclusively Partner With Industry Leader WuXi XDC For This Key IND-enabling Work*

**Tampa, FL and London – December 23, 2025** – Akari Therapeutics, Plc (Nasdaq: AKTX), an oncology biotechnology company developing antibody drug conjugates (ADCs) with novel payloads today announced the initiation of GMP manufacturing activities to support the development of AKTX-101, the Company's lead ADC program.

Akari has selected WuXi XDC, the world's leading ADC contract development and manufacturing organization (CDMO), as its partner for this critical and necessary IND-enabling work to support the initiation of clinical trials. WuXi XDC is globally recognized for its end-to-end ADC development and manufacturing capabilities and deep expertise in producing large numbers of ADCs that are currently in clinical development.

The initiation of this key manufacturing activity marks a significant advancement for AKTX-101, which incorporates Akari's novel proprietary payload PH1 that works through RNA splicing modulation. The PH1 payload represents a differentiated approach to ADC design and brings a 1-2 punch of cytotoxicity and immuno-oncology action that has the potential to significantly increase the therapeutic impact of ADCs beyond today's current options.

"Initiating GMP manufacturing of AKTX-101 is an important milestone for Akari and for AKTX-101 as we look to demonstrate the potential of our PH1 ADC payload in treating cancer patients," said Abizer Gaslightwala, President and CEO of Akari Therapeutics. "Advancing this critical project with WuXi XDC reflects our confidence in the science behind AKTX-101 and our path to the clinic. To have WuXi XDC as our key partner adds to our confidence of reaching the clinical trials quickly and efficiently and with the highest quality. This key work lays the foundation for our planned Phase 1 first-in-human study in approximately 12 months."

WuXi XDC also highlighted the importance of the collaboration with Akari and the innovative nature of Akari's ADC payload, PH1:

“We are excited to work with Akari Therapeutics on the manufacturing of AKTX-101,” said Dr. Jimmy Li, CEO of WuXi XDC. “The PH1 payload represents a novel and potentially high impact innovation in the ADC field, and we look forward to leveraging our integrated ADC platform to support the production of high-quality GMP material and help advance this promising program toward the clinic. We believe this first project with Akari could lay the groundwork for multiple ADC programs that utilize this novel payload.”

Akari and WuXi XDC are building a strategic partnership around AKTX-101, combining Akari’s innovative ADC design and payload technology with WuXi’s global leadership in ADC development and manufacturing. The resulting GMP-grade drug product is intended to support Akari’s planned Phase 1 first-in-human clinical trial, which the Company expects to initiate in late 2026 or early 2027, subject to regulatory clearance.

This manufacturing milestone underscores Akari’s continued progress in advancing its pipeline and executing on its strategy to develop differentiated ADC therapies using novel payloads that have the potential to significantly improve outcomes for cancer patients.

### **About Akari Therapeutics**

Akari Therapeutics is an oncology biotechnology company developing next-generation spliceosome payload antibody drug conjugates (ADCs). Utilizing its innovative ADC discovery platform, the Company has the ability to generate ADC candidates and optimize them based on the desired application to any target of interest. Akari’s lead candidate, AKTX-101, targets the Trop2 receptor on cancer cells and with a proprietary linker, delivers its novel PH1 payload directly into the tumor. Unlike current ADCs that use tubulin inhibitors and DNA damaging agents as their payloads, PH1 is a novel payload that is a spliceosome modulator designed to disrupt RNA splicing within cancer cells. This splicing modulation has been shown in preclinical animal models to induce cancer cell death while activating immune cells to drive robust and durable activity. In preclinical studies, AKTX-101 has shown to have significant activity and prolonged survival, relative to ADCs with traditional payloads. Additionally, AKTX-101 has the potential to be synergistic with checkpoint inhibitors and has demonstrated prolonged survival as both a single agent and in combination with checkpoint inhibitors, as compared to appropriate controls. The Company is generating validating data on its novel payload PH1 to continue advancing its lead asset, as well as other undisclosed targets with this novel payload.

For more information about the Company, please visit [www.akaritx.com](http://www.akaritx.com) and connect on [X](#) and [LinkedIn](#).

## About WuXi XDC

WuXi XDC Cayman Inc. (stock code: 2268.HK) is a globally recognized contract research, development, and manufacturing organization (CRDMO) specializing in bioconjugates. The company offers a wide range of innovative conjugation and payload-linker technologies to facilitate the development of next-generation antibody-drug conjugates (ADCs). Focused on early-stage research and development of ADCs and other bioconjugates, WuXi XDC offers comprehensive one-stop services from preclinical to commercial manufacturing. Its services cover antibody intermediates and other biologics intermediates, chemical payloads and linkers, as well as bioconjugate drug substances and drug products. For more information about WuXi XDC, please visit: [www.wuxixdc.com](http://www.wuxixdc.com).

## Cautionary Note Regarding Forward-Looking Statements

This press release includes express or implied forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, about the Company that involve risks and uncertainties relating to future events and the future performance of the Company. Actual events or results may differ materially from these forward-looking statements. Words such as “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “future,” “opportunity” “will likely result,” “target,” variations of such words, and similar expressions or negatives of these words are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. Examples of such forward-looking statements include, but are not limited to, express or implied statements regarding the ability of the Company to advance its product candidates for the treatment of cancer and any other diseases, and ultimately bring therapies to patients; the Company’s targets, plans, objectives or goals for future operations, including those related to its product candidates. These statements are based on the Company’s current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific. A number of important factors, including those described in this communication, could cause actual results to differ materially from those contemplated in any forward-looking statements. Factors that may affect future results and may cause these forward-looking statements to be inaccurate include, without limitation: the potential impact of unforeseen liabilities, future capital expenditures, revenues, costs, expenses, earnings, synergies, economic performance, indebtedness, financial condition and losses on the future prospects, business and management strategies for the management, expansion and growth of the business; risks related to global as well as local political and economic conditions, including interest rate and

currency exchange rate fluctuations; potential delays or failures related to research and/or development of the Company's programs or product candidates; risks related to any loss of the Company's patents or other intellectual property rights; any interruptions of the supply chain for raw materials or manufacturing for the Company's product candidates, including as a result of potential tariffs; the nature, timing, cost and possible success and therapeutic applications of product candidates being developed by the Company and/or its collaborators or licensees; the extent to which the results from the research and development programs conducted by the Company, and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; uncertainty of the utilization, market acceptance, and commercial success of the Company's product candidates; risks related to competition for the Company's product candidates; and the Company's ability to successfully develop or commercialize its product candidates. While the foregoing list of factors presented here is considered representative, no list should be considered to be a complete statement of all potential risks and uncertainties. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the SEC, copies of which may be obtained from the SEC's website at [www.sec.gov](http://www.sec.gov). The Company assumes no, and hereby disclaims any, obligation to update the forward-looking statements contained in this press release except as required by law.

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