Q32 Bio Presents Preclinical Data Supporting Next Generation Complement Inhibitor, ADX-097, at the American Society of Nephrology Kidney Week 2021

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- Data demonstrate ADX-097's ability to precisely target complement blockade to diseased tissue

- In multiple renal disease models, ADX-097 potently inhibits disease-causing complement activation while avoiding systemic complement inhibition

CAMBRIDGE, Mass., Nov. 8, 2021 /PRNewswire/ -- Q32 Bio, a clinical stage biotechnology company developing biologic therapeutics to restore immune homeostasis, today announced preclinical data from the Company's lead program for innate immunity, ADX-097, presented at the American Society of Nephrology (ASN) Kidney Week 2021 on November 5, 2021. These data validate the mechanism of action of ADX-097, a first-in-class fusion protein, and demonstrate the ability to potently inhibit disease-causing complement activation in a targeted manner while avoiding systemic complement inhibition.

"Q32 Bio's approach to the treatment of complement disorders is fundamentally different from that of other companies in that our therapies target the tissue, not the systemic complement system," said Shelia Violette, Ph.D., Founder, Chief Scientific Officer and President of Research of Q32 Bio. "The data presented at ASN demonstrate the potential for tissue targeting to yield greater therapeutic potency while avoiding systemic complement inhibition. As a result, we believe ADX-097 has the potential to safely deliver potent and durable efficacy to diseased tissue where complement is overactive, which could provide a significant improvement over currently available complement inhibitors and enable a more convenient treatment paradigm for patients."

The data evaluate the potency and durable response of ADX-097, a humanized anti-C3d monoclonal antibody linked to two moieties of the first five consensus repeats of the complement negative regulatory protein human factor H (fH_{1-5}), designed to target complement inhibition to diseased tissue. Key results are as follows:

- In factor H knockout mice, C3d-targeted fH_{1-5} potently inhibits glomerular complement activation. The blockade in tissue is achieved at circulating exposures that avoid systemic complement inhibition. Furthermore, these data show that complement inhibition persists for at least one week after a single subcutaneous dose.
- In a head-to-head analysis, ADX-097 (C3d-targeted fH_{1-5}) more potently inhibits glomerular complement activity and reduces proteinuria as compared to non-targeted fH_{1-5} in the Passive Heymann Nephritis model of membranous nephropathy. These data demonstrate the critical role of ADX-097's tissue targeting in enhancing potency as compared to non-targeted constructs.

"We are extremely pleased with these early data and are keenly focused on advancing ADX-097 into the clinic next year," said Michael Broxson, Chief Executive Officer of Q32 Bio. "We look forward to evaluating additional complement programs that similarly leverage favorable routes of administration and dosing regimens that reduce treatment burden on patients."

About ADX-097

ADX-097 is a first-in-class fusion protein that Q32 Bio is developing to restore homeostasis to the innate immune response through targeted regulation of complement directly in diseased tissues without long-term systemic blockade. In preclinical studies, ADX-097 has proven *in vivo* distribution to affected tissues/organs, durable tissue pharmacokinetics (PK)/pharmacodynamics (PD), robust *in vivo* efficacy, and attractive drug properties. Q32 Bio plans to initiate first-in-human trials for ADX-097 in the first half of 2022.

About Q32 Bio

Q32 Bio is a clinical stage biotechnology company developing biologic therapeutics targeting powerful regulators of the innate and adaptive immune systems to re-balance immunity in severe autoimmune and inflammatory diseases. Q32 Bio's lead programs, focused on the IL-7 / TSLP receptor pathways and complement system, address immune dysregulation to help patients take back control of their lives.

The company's most advanced program, ADX-914, is a fully human anti-IL-7Ra antibody. The IL-7 and TSLP pathways have been genetically and biologically implicated in driving several T cell-mediated pathological processes in numerous autoimmune diseases. Q32 Bio has completed dosing in a Phase 1 trial of ADX-914 in healthy volunteers and plans to initiate Phase 2 studies in in the first half of 2022.

Q32 Bio's lead program for innate immunity, ADX-097, is based on a pioneering approach enabling tissue-targeted regulation of the complement system without long-term systemic blockade – a key differentiator versus current complement therapeutics. Q32 Bio plans to initiate first-in-human trials for ADX-097 in the first half of 2022. For more information, please visit www.Q32bio.com.

Contact

Investors: Brendan Burns
Media: Sarah Sutton
Argot Partners
212.600.1902
Q32Bio@argotpartners.com

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