Q32 Bio Presents Preclinical Data Highlighting the Design and Characterization of Lead Program for Innate Immunity, ADX-097, at the 28th International Complement Virtual Workshop 2021

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- C3d targeted fusion proteins enable highly specific tissue-targeted complement system inhibition

- ADX-097 has the potential to provide increased potency, decreased dosing frequency and improved safety in severe inflammatory and autoimmune diseases

CAMBRIDGE, Mass., Dec. 13, 2021 /PRNewswire/ -- Q32 Bio, a clinical stage biotechnology company developing biologic therapeutics to restore immune homeostasis, today announced preclinical data for the Company's lead program for innate immunity, ADX-097. Three posters were presented at the 28th International Complement Virtual Workshop on December 8-9, 2021. These data, which highlight the design and characterization of ADX-097, elucidate the ability of ADX-097 to potently deliver tissue targeted complement inhibition and disease modifying efficacy without systemically affecting the complement system.

"The data shared at the 28th International Complement Virtual Workshop highlight unique properties around ADX-097, a novel construct that enables highly specific and potent tissue targeted complement inhibition, that have the potential to provide decreased dosing frequency and improved safety for individuals suffering from a range of severe inflammatory and autoimmune diseases," said Shelia Violette, Ph.D., Founder, Chief Scientific Officer and President of Research of Q32 Bio. "Furthermore, signals of efficacy derived from our preclinical models strengthen our conviction in the design and drug characteristics of ADX-097, which we believe has strong therapeutic potential in multiple indications, and we are keenly focused on advancing this program into the clinic."

Key results across the three poster presentations, entitled "Design and characterization of C3d targeted fusion proteins for tissue localized inhibition of complement activation," "Design and characterization of ADX-097: A C3d targeted antibody – fH_{1-5} fusion protein for the treatment of complement alternative pathway driven disease" and "C3d-targeted factor H achieves potent tissue-directed complement inhibition and disease-modifying efficacy without affecting systemic complement," are as follows:

- Across a range of negative regulatory proteins, Q32 Bio demonstrated the capability to potently inhibit the classical, lectin and alternate pathways. Further, these fusion proteins can distribute in vivo to sites where C3d is deposited and inhibit complement activity, providing an opportunity to deliver pathway-specific, tissue-targeted complement inhibitors while avoiding systemic complement system blockade. This approach has the potential to provide increased potency, decreased dosing frequency and improved safety.
- ADX-097 was designed and engineered to optimize binding affinity, functional activity and developability properties. The biochemical and functional profile, consisting of 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}), demonstrate excellent tissue localization, potent inhibition of the alternative complement pathway and attractive drug-like properties. ADX-097 has therapeutic potential in multiple indications with unmet need.
- In preclinical models, including data from factor H knockout mice and the Passive Heymann Nephritis model of membranous nephropathy, C3d-mediated tissue targeting of fH_{1-5} results in potent, durable and efficacious local alternative pathway complement blockade, while avoiding systemic complement inhibition. Further, these data demonstrate the therapeutic potential of ADX-097 and support future clinical studies.

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.

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