Q32 Bio Presents New Preclinical Data at the International Society of Nephrology Frontiers Meeting Demonstrating the Therapeutic Potential of ADX-097

June 23, 2022

Data show that C3d-mediated tissue targeting of factor H results in potent, durable and efficacious local complement blockade without systemic complement inhibition

WALTHAM, Mass., June 23, 2022 /PRNewswire/ -- Q32 Bio, a clinical stage biotechnology company developing biologic therapeutics to restore immune homeostasis, today announced that the Company presented new preclinical data demonstrating the therapeutic potential of ADX-097, Q32's lead program for innate immunity. The data was presented by Stefan Wawersik, Ph.D., Q32's Vice President of Research, in a poster presentation titled "C3d-Directed Factor H Targeting Delivers Potent and Durable Complement Inhibition and Disease-Modifying Efficacy in Kidney and Skin Without Inhibiting Systemic Complement," at the International Society of Nephrology (ISN) "Complement-related kidney diseases: Classification, genetics and treatment" Frontiers Meeting held in Bergamo, Italy.

"Q32 is developing ADX-097 as a potent tissue targeted complement regulator that spares systemic complement blockade," said Shelia Violette, Ph.D., Founder and Chief Scientific Officer of Q32 Bio. "The data presented at the ISN Frontiers Meeting provides important validation of our approach, describing how, in multiple preclinical models, including non-human primates, ADX-097 effectively inhibited complement activation in injured/diseased tissue while minimizing systemic blockade."

Study Results

ADX-097 is a bi-functional fusion protein comprising a humanized anti-C3d monoclonal antibody linked to two moieties of the first five consensus repeats of factor H and was designed to enable local inhibition of complement activation in diseased tissue while avoiding systemic complement blockade.

The study examined ADX-097's therapeutic potential across multiple preclinical models and target expression in human renal disease biopsies. This included characterizing: 1) circulating and tissue pharmacokinetics and pharmacodynamics (PK/PD) of ADX-097 in a non-human primate model of UVB-induced complement activation in the skin; 2) circulating and tissue PK/PD of a mouse surrogate, ADX-118, in a factor H-/- mouse model of complement activation in the kidney; 3) circulating and tissue PK/PD and efficacy for ADX-097 in a rat Passive Heymann nephritis model of membranous nephropathy; and 4) expression of the C3d target and C3 complement activation in human renal disease biopsies by immunohistochemistry.

Collectively, the study results suggest that C3d-mediated tissue targeting drives ADX-097 potency and efficacy. They demonstrate C3d deposition and C3 complement activation by immunohistochemistry across several human renal diseases, indicating the broad therapeutic potential of ADX-097. Finally, they show that C3d-mediated tissue targeting of factor H results in potent, durable and efficacious local AP complement blockade without systemic complement inhibition.

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 a Phase 2 program in the second 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 is currently conducting a first-in-human, Phase 1, ascending dose (SAD/MAD) clinical study of ADX-097 for the treatment of complement disorders. For more information, please visit www.Q32bio.com.

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