AXT107 Restores Healthy, Non-Leaky Vasculature in the Eye by Inhibiting VEGFR2 and Activating Tie2, the Two Clinically Validated Pathways in Diseases of the Retina

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BALTIMORE, MD – AsclepiX Therapeutics, Inc., a biopharmaceutical company focused on developing vital new peptide therapies, including a novel collagen IV-derived peptide called AXT107, announces the publication of a study highlighting the immense therapeutic potential of the investigational therapeutic agent, AXT107, for patients affected by Diabetic Macular Edema (DME), Neovascular Age-Related Macular Degeneration (wet AMD) and other diseases of the retina. AXT107 is an investigational therapeutic agent and is currently not approved for clinical use and is currently being studied for various retinal pathologies.

AXT107 exhibited a dual mechanism of action as a monotherapy, disrupting a key component of the Vascular Endothelial Growth Factor (VEGF) signaling pathway while also activating the Tie2 pathway that is integral to maintenance of vascular homeostasis.

A single monotherapy injection of AXT107 demonstrated in vivo efficacy lasting for many months, suggesting patients may require only 1 to 2 injections per year.

To date, AXT107 has demonstrated excellent safety, superior efficacy and longer durability in in vivo models compared to current standard of care treatments.

Previously published research with AXT107 demonstrated that the novel agent is also a potent inhibitor of Vascular Endothelial Growth Factor (VEGF) Receptor 2 (VEGFR2) via interaction with another integrin protein, \( \alpha v \beta 3 \), meaning it blunts or obviates a crucial component of VEGF, turning off VEGF signaling that would otherwise lead to new vessel growth and vessel leakage. Combined with the latest findings, these data collectively indicate that AXT107 has a unique mechanism of action that leads to efficacy along two critical disease pathways to potentially provide a distinct and more efficacious therapeutic benefit than currently available standard of care. By simultaneously inhibiting VEGFR2 signaling and activating Tie2 signaling as a monotherapy, AXT107 modulates both clinically validated pathways implicated in increasing vascular leakage and neovascularization in ocular diseases and thus could overcome the ceiling of efficacy reached by current anti-VEGF therapies.

“The importance of identifying new therapeutic strategies in DME, wet AMD, and other diseases of the retina cannot be underscored enough. While the current approach, repeated intravitreal injection of anti-VEGF agents, which targets only a single component of disease, has proven effective, some patients demonstrate a sub-optimal or poor response, while others do not respond at all; many of those who respond initially eventually progress to loss of vision. If future studies continue to confirm the efficacy and safety profile of AXT107 shown in early in vivo studies, retina specialists and their patients could benefit from this treatment that may impact multiple pathways with the potential for increased efficacy and durability for these common retinal pathologies,” said Jeffrey S. Heier, MD, Director of Retina Research at Ophthalmic Consultants of Boston and a member of the AsclepiX Therapeutics Scientific Advisory Board.

Upon injection, AXT107 forms a gel in the vitreous remote from the visual axis. Studies in animal models indicate that the gel does not interfere with normal optic nerve function, and instead, provides for long duration of action and sustained efficacy, with evidence that a single injection continues to provide benefit for many months. That means patients may require only 1 to 2 injections of AXT107 per year, which would represent a significant reduction in the treatment burden associated with anti-VEGF agents that must be re-injected every 1 to 3 months.

AXT107 has also demonstrated excellent safety in animal and toxicology studies for 15 months.
“AXT107 may be a potential game changer for the millions of patients affected by DME, wet AMD and other diseases of the retina,” said Wendy Perrow, MBA, CEO of AsclepiX Therapeutics, Inc. “This recent study has helped to elucidate the mechanisms of action of AXT107 while also underscoring the role it plays in turning Ang2, which is typically an antagonist of the Tie2 pathway, into a Tie2 agonist. Since Ang2 levels are elevated in ischemic ocular conditions like DME and wet AMD, there is an indication that AXT107 may represent a more effective approach to treating these conditions than current standard of care—and indeed, it is potentially more efficacious with longer duration than other combinatorial and monotherapy approaches under investigation that target the Tie2 pathway.” AXT107 is an investigational therapeutic agent and has not been evaluated for safety and efficacy by the U.S. Food and Drug Administration or other regulatory agencies.

References:

About AsclepiX Therapeutics
AsclepiX Therapeutics Inc. is transforming the treatment of retinal diseases and cancer with a singular focus on a novel peptide platform with the power to inhibit and potentially even reverse disease progression. The mechanism of action of AXT107 targets multiple pathways, including inhibiting vascular endothelial growth factor receptor 2 (VEGFR2) and activating Tie2, two pathways that promote formation of blood vessels and leakage of fluid in the diseased retina that may be dosed 1-2 times per year. AsclepiX is initially focused on ocular diseases currently treated with anti-VEGF monotherapies. Learn more at www.asclepix.com.

Forward-Looking Statements
This press release contains “forward-looking statements” concerning the development of AsclepiX Therapeutics, Inc. products, the potential benefits and attributes of such products, and the company’s expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. AsclepiX Therapeutics, Inc. undertakes no obligation to update any forward-looking statements for any reason.

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