Skye Bioscience Establishes Partnership with Arecor Therapeutics to Develop Enhanced Formulation of Obesity Candidate Nimacimab

Proprietary formulation technology being applied to potentially enhance properties of nimacimab

SAN DIEGO, May 19, 2025 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (Nasdaq: SKYE) ("Skye"), a clinical-stage biotechnology company focused on unlocking new therapeutic pathways for obesity and other metabolic health disorders, today announced a formulation development collaboration with Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical company advancing today's therapies to enable healthier lives. The partnership aims to develop a higher concentration formulation of Skye's CB1 inhibitor, nimacimab, using Arecor's proprietary formulation technology platform, Arestat[™].

Skye is evaluating nimacimab, a first-in-class CB1-inhibiting monoclonal antibody, in its Phase 2a CBeyond[™] clinical trial in patients with obesity and overweight. Data from the initial 26-week treatment period is anticipated in late Q3 or early Q4 2025.

Under the terms of the agreement, Skye will fund Arecor's development activities with the option to license rights to the new proprietary formulation of nimacimab and associated intellectual property to further develop and commercialize the product.

Sarah Howell, Chief Executive Officer of Arecor, said: "We are pleased to partner with Skye to support the development of a novel, enhanced formulation of nimacimab, a promising first-in-class candidate with the potential to address significant unmet needs in metabolic disease. This collaboration highlights the strength of our proprietary Arestat[™] technology in enabling the development of enhanced therapeutic products that can improve patient outcomes and supports our strategy of bringing innovative medicines to market that address significant unmet patient needs in high-value markets."

Tu Diep, Chief Operating Officer of Skye, said: "Approved weight loss drugs have issues with tolerability and adherence, while the small molecule CB1 inhibitors raise concerns about cumulative exposure-related neuropsychiatric toxicities. Nimacimab already has an advantageous pharmacokinetic profile and to date it does not pose these issues. It has a potentially best-in-class half-life of 18–21 days--substantially longer than GLP-1-based therapies--and is being evaluated in a Phase 2a study with once-weekly dosing. Serving our goal of continuous innovation, we are pleased to work with Arecor on the goal of further enhancing nimacimab to improve patient compliance and treatment outcomes."

About Arecor

Arecor Therapeutics plc is a globally focused biopharmaceutical company transforming

patient care by bringing innovative medicines to market through the enhancement of existing therapeutic products. By applying our innovative proprietary technology platform, Arestat[™], we are developing an internal portfolio of proprietary products in diabetes and other indications, as well as working with leading pharmaceutical and biotechnology companies to deliver therapeutic products. The Arestat[™] platform is supported by an extensive patent portfolio. For further details please see our website, <u>www.arecor.com</u>.

About Skye Bioscience

Skye is focused on unlocking new therapeutic pathways for metabolic health through the development of next-generation molecules that modulate G-protein coupled receptors. Skye's strategy leverages biologic targets with substantial human proof of mechanism for the development of first-in-class therapeutic candidates with clinical and commercial differentiation. Skye is conducting a Phase 2a clinical trial (ClinicalTrials.gov: NCT06577090) in obesity for nimacimab, a negative allosteric modulating antibody that peripherally inhibits CB1. This study is also assessing the combination of nimacimab and a GLP-1R agonist (Wegovy®). For more information, please visit: www.skyebioscience.com. Connect with us on X and LinkedIn.

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FORWARD LOOKING STATEMENTS

This press release contains 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. In some cases, forward-looking statements can be identified by terminology including "anticipated," "plans," "goal," "focus," "aims," "intends," "believes," "can," "could," "challenge," "predictable," "will," "would," "may" or the negative of these terms or other comparable terminology. These forward looking statements include, but are not limited to statements regarding the pharmacokinetic and pharmacodynamic profile of nimacimab and statements regarding the timing of receipt of final data from Skye's Phase 2 obesity study of nimacimab. Such statements and other statements in this press release that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition, and stock price could be materially negatively affected. We operate in a rapidly changing environment, and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements the Company may make. Risks and uncertainties that may cause actual results to differ materially include, among others, our capital resources, uncertainty regarding the results of future testing and development efforts and other risks that are described in the Company's periodic filings with the Securities and Exchange Commission, including in the "Risk Factors" section of Skye's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Except as expressly required by law, Skye disclaims any intent or obligation to update these forward-looking statements.



Source: Skye Bioscience, Inc.