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# **Skye Bioscience and Tautomer Bioscience Enter Exclusive License for SBI-100 for Development and Sale of Products for Chronic Pain and Other Indications in South Africa and Rest of Africa**

San Diego, California and Johannesburg, South Africa--(Newsfile Corp. - December 5, 2023) - Skye Bioscience, Inc. (OTCQB: SKYE) ("Skye"), a pharmaceutical company developing drugs targeting the endocannabinoid system, and Tautomer Bioscience (Pty) Limited ("Tautomer"), a privately-owned biopharmaceutical company focused on addressing unmet medical needs in oncology, pain management and infectious diseases, announced today that they have entered into an agreement under which Skye is providing Tautomer with an exclusive license to develop and commercialize Skye's proprietary THC prodrug, SBI-100, as a novel suppository application for chronic intractable pain and other indications ("Tautomer Products") in South Africa and the rest of Africa.

Under the terms of the agreement Tautomer has the right to develop and commercialize products based on Skye's active pharmaceutical ingredient, SBI-100, formulated as a suppository, and related intellectual property. Tautomer is responsible for all formulation, preclinical and clinical development, drug product manufacturing and regulatory costs. Skye will receive development milestones, sales milestones, and tiered double-digit royalties on net product sales and will be compensated for all development work, including the supply of SBI-100 active pharmaceutical ingredient ("API") for the Tautomer Products. Under the terms of the agreement Tautomer will also purchase Skye shares in open market transactions complying with Rule 10b-18 of the Securities Exchange Act of 1934, as amended. Skye has retained certain rights and options to obtain rights to the future use of new jointly developed intellectual property and other intellectual property owned or controlled by Tautomer related to SBI-100.

"Chronic pain causes disability, with significant personal and societal cost. According to PAIN SA, chronic pain affects 20% of the adult population in South Africa, with women and the elderly the worst affected. Our region, like the rest of the world, requires more non-opioid alternatives to address this growing epidemic," said Martin Magwaza, Managing Director of Tautomer. "South Africa has a progressive regulatory, legislative, and academic environment which embraces cannabinoids as therapies. Tautomer believes that the SBI-100 technology is an ideal candidate to harness the power of the endocannabinoid system to manage chronic pain as it provides predictable dosing and improved bioavailability, avoids first pass metabolism, and may potentially have safer outcomes."

There is growing evidence and interest in the role of the endocannabinoid system, in particular activation of the CB1 receptor ("CB1"), for the treatment of chronic pain. Multiple medical reviews have demonstrated that cannabis use can alleviate pain symptoms while

potentially reducing or even substituting opioid and non-opioid pharmacologic pain treatments. Importantly, CB1 is highly expressed in areas of the brain and spinal cord associated with pain as well as in the dorsal root ganglia of the peripheral nervous system. With this widespread distribution of these receptors in such critical pain-processing regions, it has long been postulated that cannabinoids such as THC can directly modulate pain. However, the presence of bioavailability and safety issues, including THC's psychotropic side effects, associated with previously used methods of delivery have in the past considerably hampered the development of cannabinoids to treat chronic pain. There is a need for pharmaceutical dosage forms that deliver the therapeutic effects of THC and minimize adverse effects.

Skye's research has demonstrated that a THC prodrug delivered as a suppository offers significantly improved bioavailability, resulting in better pharmacokinetics and potentially improved safety. Tautomer believes that Skye's data is sufficient to support a regulatory filing in South Africa for the chronic pain indication.

"The persistent global challenge of chronic pain, despite the array of non-pharmacologic and pharmacologic treatment options, in our view creates a need for new analgesics with novel mechanisms of action. We commend the Tautomer team for their foresight in identifying the potential of SBI-100 to address this unmet medical need through an innovative formulation. Tautomer has a strong track record and a history of entrepreneurial success in medical product commercialization both in South Africa and across the broader African continent, and we are pleased to establish this agreement with them," said Punit Dhillon, CEO and Chair of Skye. "While Skye is developing its differentiated CB1-targeting pharmaceutical drugs for ophthalmic and cardiometabolic conditions, we also recognize the significant opportunities for our CB1 agonist in the realm of chronic pain and other medical indications. This a great opportunity to realize incremental value from our API using alternative drug delivery systems.

"We believe that Tautomer can pursue a potentially accelerated path to develop and obtain regulatory approval for new products with SBI-100 in South Africa in order to offer patients with chronic pain a non-opioid treatment alternative. We look forward to providing assistance to Tautomer to bring this product to market in a region with a significant unmet medical need," added Mr. Dhillon.

This license agreement is subject to approval by the Financial Surveillance Department of the South African Reserve Bank, as may be required in terms of the Exchange Control Regulations (issued in terms of the Currency and Exchanges Act 9 of 1933) for any of the transactions contemplated in this agreement.

## **Pain Market in South Africa**

South African national surveys have reported a high prevalence of chronic pain in the adult population. Prevalence rates range from 14% to 37%. Women and the elderly are the worst affected. Chronic pain comes at a high cost to the individual as well as the health system and the economy at large. Furthermore, some reports have stated that as many as 50% of chronic pain sufferers do not achieve adequate pain relief, despite treatment. There is a need for more effective therapies for the management of chronic pain.

## **About SBI-100**

SBI-100 is a proprietary amino acid ester prodrug of delta-9-tetrahydrocannabinol ("THC") that functions as an agonist, or activator, of the endocannabinoid system's CB1 receptor. This receptor plays an integral role in overall endocannabinoid system activities involved in modulating sleep, hunger/metabolism, pain, and other functions.

### **About Tautomer**

Tautomer Bioscience is a privately owned, fully integrated health technology company based in Johannesburg, South Africa. Through our network of strategic partners, we engage in the development, manufacturing, and distribution of high-quality nuclear medicine-based therapies and diagnostics. Our primary focus in healthcare is to address the unmet medical needs in oncology, pain management, infectious diseases. For more information, please visit [www.tautomer-bioscience.com](http://www.tautomer-bioscience.com).

### **About Skye Bioscience**

Skye is focused on unlocking the pharmaceutical potential of the endocannabinoid system to treat diseases with inflammatory, fibrotic, and metabolic processes. Backed by leading life science venture investors, Skye's strategy leverages biologic targets with substantial human proof of mechanism for the development of first-in-class therapeutics with significant clinical and commercial differentiation. Nimacimab, a negative allosteric modulating antibody, inhibits peripheral CB1 with a favorable safety and tolerability profile in a Phase 1 study. Skye plans to start a Phase 2 cardiometabolic-focused study encompassing obesity for nimacimab in H1 2024. SBI-100 Ophthalmic Emulsion, a CB1 agonist, is currently being studied in a Phase 2 study with patients with glaucoma and ocular hypertension. For more information, please visit: <https://www.skyebioscience.com>.

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### **FORWARD-LOOKING STATEMENTS**

This press release contains forward-looking statements, including statements regarding our product development, business strategy, timing of clinical trials and commercialization of cannabinoid-derived therapeutics. 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. 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. 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 Risk Factors section of Skye's most recent annual or quarterly report filed with the Securities and Exchange Commission. Except as expressly required by law, Skye disclaims any intent or obligation to update these forward-looking statements.



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