March 30, 2023

GSK and SCYNEXIS Announce an Exclusive Agreement to Commercialise and Further Develop Brexafemme (ibrexafungerp), a Novel, First-in-Class Medicine to Treat Fungal Infection

- *Brexafemme* complements GSK's industry-leading infectious disease portfolio with an FDA approved treatment for vulvovaginal candidiasis
- SCYNEXIS will receive an upfront payment of $90 million with future performance-based milestone payments and tiered royalties
- SCYNEXIS retains rights to all other assets derived from enfumafungin, with GSK having a right of first negotiation to these pre-clinical and discovery stage assets
- SCYNEXIS to host an investor call and webcast at 8:30 a.m. EDT today

LONDON and JERSEY CITY, N.J., March 30, 2023 (GLOBE NEWSWIRE) -- GSK plc (LSE/NYSE: GSK) and SCYNEXIS, Inc. (NASDAQ: SCYX), today announced they have entered into an exclusive licence agreement for *Brexafemme* (ibrexafungerp tablets), a US FDA approved, first-in-class antifungal for the treatment of vulvovaginal candidiasis (VVC) and for reduction in the incidence of recurrent VVC (RVVC). This exclusive licence agreement gives GSK rights to commercialise *Brexafemme* for VVC and RVVC while continuing to develop ibrexafungerp, which is in phase III clinical trials for the potential treatment of invasive candidiasis (IC), a life-threatening fungal infection.

Infectious diseases and HIV represent around two-thirds of GSK's pipeline.*Brexafemme* complements GSK's first or best-in-class portfolio alongside late-stage antibiotics gepotidacin, potentially the first novel antibiotic for uncomplicated urinary tract infections (uUTI) in over 20 years, and tebipenem, a potential new treatment of complicated urinary tract infections (cUTI).

Luke Miels, Chief Commercial Officer, GSK said: "The challenge of antimicrobial resistance includes increasing rates of multi-drug resistant fungal infections. *Brexafemme* is a novel, approved antifungal medicine with a broad spectrum of activity against existing and emerging resistant strains of fungi. In addition, the transaction consolidates GSK's synergistic portfolio of innovative late-stage antibiotics."

VVC affects up to 75% of women at least once, with 40-45% having two or more episodes. *Brexafemme* has a distinct mechanism of action whereby it kills the fungus, as opposed to some antifungals which inhibit fungal growth. It is the only oral antifungal US FDA-approved treatment for VVC and reduction of RVVC. With rates of resistance to other antifungal treatments rising, *Brexafemme* addresses a clear unmet need for new oral treatments.

David Angulo, M.D., President and Chief Executive Officer of SCYNEXIS said:"This agreement represents a major milestone for SCYNEXIS, maximising *Brexafemme*'s commercial potential in VVC and further validating our vision of the critical role for this first-in-class antifungal in invasive infections. We are thrilled to partner with GSK on this high-potential asset and will continue progressing ibrexafungerp's phase III programme in invasive candidiasis (IC)."

IC is a life-threatening infection that affects the blood or internal organs. There are around 750,000 cases of IC every year worldwide.[ii] In the US, it is one of the most common causes of bloodstream infections in hospitalised patients and can lead to more extended hospital stays and higher associated costs.

Financial terms
Under the terms of the agreement, GSK will make an upfront payment to SCYNEXIS of $90 million, plus additional potential milestone-based payments totalling $503 million.

GSK will pay up to $245.5 million if specific development, regulatory, and commercial milestones associated with the IC indication are successfully completed. A further $15 million milestone will be paid upon successful US FDA approval of an additional indication.

GSK will pay sales-related milestone payments based on achieving a certain commercial performance of up to $242.5 million, and mid-single digit to mid-teen digit tiered royalties on the totality of sales across all indications (in both cases with the top tier based on achieving net sales greater than $1 billion).

GSK will also receive an exclusive licence to develop ibrexafungerp and commercialise *Brexafemme* in all countries except the greater China region and certain other countries already out-licensed by SCYNEXIS to third parties. Under the licence agreement, SCYNEXIS will continue executing the phase III programme for IC and other ongoing trials.

SCYNEXIS retains rights to all other assets derived from enfumafungin. As part of this exclusive licence agreement, GSK has been granted a right of first negotiation to these compounds.

This agreement is conditional upon customary conditions including review by the appropriate regulatory agencies under the Hart-Scott-Rodino Act.

Aquilo Partners, L.P. is acting as financial advisor and Cooley LLP as legal advisor to SCYNEXIS on this transaction.

SCYNEXIS will host a conference call and webcast at 8:30 a.m. EDT today. Conference call and webcast details: Investors dial: (877) 704-4453 or (201) 389-0920
Conference ID: 13729053
Call Me™ Feature: Link
Webcast: Link

A live audio webcast can be accessed by visiting the Investor Relations section of the Company's website, www.scynexis.com. A replay of the webcast will be archived on the SCYNEXIS website for 90 days following the event.

About *Brexafemme* (ibrexafungerp tablets)
Brexafemme (ibrexafungerp tablets) is a novel oral glucan synthase inhibitor with a broad spectrum of activity including against emerging resistant threats. Its mechanism of action is similar to echinocandins, with fungicidal action against yeast (meaning it kills the fungus), versus fluconazole which is fungistatic (meaning it inhibits fungal growth). It was first approved in the US in 2021 for the treatment of VVC and is the first and only oral antifungal approved for both the treatment of VVC and the reduction of the incidence of RVVC. *Brexafemme* has proven activity against WHO-designated priority fungal pathogens such as *Candida albicans*. In addition, ibrexafungerp has shown activity against *Candida auris*, another WHO-designated priority fungal pathogen.

Prescribing information is available here.

About VVC and RVVC
VVC is a widespread vaginal infection primarily caused by a fungus called *Candida albicans*. Surveys suggest that VVC affects up to 75% of women once in their life, and 40%–45% have two or more episodes[i]. RVVC is a debilitating, long-term condition that can severely affect the quality of life of affected women.

Although not life-threatening, VVC does cause severe itching, soreness, and vaginal irritation, interfering with normal sexual relations. These symptoms and manifestations are considerably magnified when attacks are frequent and recurrent and when the disease is refractory to conventional therapy.[iii]

For the 30% of patients with complicated VVC, which includes recurrent, azole-resistant or refractory VVC, there are limited treatment options, with current guidelines limited to using the same treatment for a longer duration.[iii]

About IC
IC is a life-threatening fungal infection caused by *Candida* that affects the blood or internal organs. In the US, it is one of the most common causes of bloodstream infections in hospitalised patients, leading to longer hospital stays, higher associated costs, and death. People at risk include patients with a prolonged stay in an Intensive Care Unit and those with a weakened immune system, e.g., chemotherapy or organ transplant.[iv]

About SCYNEXIS
SCYNEXIS, Inc. (NASDAQ: SCYX) is a biotechnology company pioneering innovative medicines to help millions of patients worldwide overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant. SCYNEXIS scientists are developing the company's lead asset, ibrexafungerp (formerly known as SCY-078), as a broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. The U.S. Food and Drug Administration (FDA) approved BREXAFEMME® (ibrexafungerp tablets) on June 1, 2021, for its first indication in vulvovaginal candidiasis (VVC), followed by a second indication on November 30, 2022, for reduction in the incidence of recurrent VVC. Late-stage clinical investigation of ibrexafungerp for the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. Additional assets derived from enfumafungin are currently in pre-clinical and discovery phase. For more information, visit www.scynexis.com.

GSK in infectious diseases
Infectious diseases and HIV represent around two-thirds of GSK's pipeline and its primary focus for R&D. In antibiotics, gepotidacin is a late-stage potential treatment for uncomplicated urinary tract infections (uUTI) and could be the first novel oral antibiotic for uUTI in more than 20 years. In addition, in September 2022, GSK entered into an exclusive licence agreement with Spero Therapeutics, Inc. to add tebipenem HBr, another late-stage antibiotic and potential treatment for complicated urinary tract infections (cUTI), to its pipeline.

About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company.

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GSK cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors" in the company's Annual Report on Form 20-F for 2022, GSK's Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

SCYNEXIS Forward-Looking Statements

Statements contained in this press release regarding expected future events or results are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These and other risks are described more fully in SCYNEXIS' filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, including in each case under the caption "Risk Factors," and in other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. SCYNEXIS undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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[i] Vulvovaginal Candidiasis - STI Treatment Guidelines (cdc.gov) Accessed March 2023
[ii] Bongomin F, et al. J Fungi (Basel) 3(4):57. Published: 18 October 2017
[iii] Willems HME, et al. J Fungi (Basel). 2020;6(1):27. Published 2020 Feb 25
[iv] www.cdc.gov/fungal/diseases/candidiasis/invasive/definition.html

Source: Scynexis