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Sonnet BioTherapeutics Inc. Enters into Licensing Agreement with Alkem Laboratories Limited to Develop and Commercialize SON-080 for Diabetic Peripheral Neuropathy (DPN) in India

Sonnet to receive \$1.0 million in upfront payment and up to an additional \$1.0 million in milestone payments with a royalty in the low double digits on net sales, less certain expenses, in the India market

Alkem to fund, develop and commercialize SON-080 for the treatment of DPN in India and commercialize SON-080 for the treatment of Chemotherapy Induced Neuropathy (CIPN) and Autonomic Neuropathy in India

The estimated market size of diabetic neuropathy in India was \$120.3 million in 2023 and is expected to reach \$246.7 million by 2030

Sonnet recently announced data from the completed Phase 1b portion of its ongoing Phase 1b/2a clinical trial evaluating SON-080 for CIPN

Pankaj Mohan, CEO of Sonnet discusses what this transaction means in a Virtual Investor "What This Means" segment; [access here](#)

PRINCETON, NJ, Oct. 09, 2024 (GLOBE NEWSWIRE) -- Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, today announced that it has entered into a licensing agreement (the "Licensing Agreement") with Alkem Laboratories Limited ("Alkem") for the research, development, manufacturing, marketing and commercialization of its molecule SON-080 for the treatment of diabetic peripheral neuropathy (DPN) in India and the manufacturing, marketing and commercialization of chemotherapy induced neuropathy (CIPN) and autonomic neuropathy in India. SON-080 has the same mechanism of action for these three neuropathies. Additionally, the Company announced the release of a "What This Means" segment to discuss the transaction which is now available [here](#).

SON-080 is Sonnet's proprietary version of recombinant human Interleukin-6 (rhIL-6) that builds upon previous work with atexakin alfa. Under the terms of the Licensing Agreement, Alkem will pay Sonnet \$1.0 million in upfront payments and up to an additional \$1.0 million in milestone payments as set forth in the Licensing Agreement. Additionally, Sonnet is entitled to receive a royalty equal to a percentage in the low double digits of the net sales of the product upon commercialization of SON-080 in India less certain expenses as set forth in the Licensing Agreement. Alkem will conduct all clinical trials it believes appropriate to obtain

regulatory approval in India for SON-080 for the treatment of DPN. Upon payment of a Clinical Data Access fee for Phase 2 and Phase 3 clinical trials, Sonnet will be able to use this data for partnering in any geography outside of India.

Pankaj Mohan, Founder and Chief Executive Officer of Sonnet, commented, “We are excited to partner with Alkem and look forward to advancing SON-080 into Phase 2 clinical development. We believe that Alkem is the ideal partner with significant experience and expertise. Additionally, the data generated from Alkem’s planned Phase 2 study will enable us to establish additional partnerships in other key markets for a clinical data access fee and potentially provide patients with DPN a much-needed therapeutic option. We believe DPN represents a significant unmet medical need, with a global market projected to reach approximately \$6.8 billion by 2030.”

Dr. Akhilesh Sharma, President and Chief Medical Officer of Alkem added, “We are very pleased to partner with Sonnet for this important program. We believe SON-080 is a unique asset that has demonstrated promising disease modification potential for DPN a high unmet medical need. There is a large prevalence of DPN in India, which we believe underscores the need for its development in this territory and potential value.”

DPN is a painful and extremely disabling disease that typically occurs in about 50% of diabetic patients. Current therapeutics focus primarily on pain symptoms due to lack of modulation treatments, however, such treatments do not address the non-pain symptoms resulting from nerve degeneration. Low dose IL-6 has been shown to stimulate peripheral nerve growth in preclinical models, thereby ameliorating motor and sensory functions and normalizing the associated pain or sensation disturbance of neuropathy.

SON-080 has undergone many years of development, in which previous clinical trials have generated safety data from over 200 patients. SON-080 has demonstrated compelling preclinical efficacy data in both DPN and CIPN, including reproducibly demonstrating the ability to prevent the development of neuropathy and reverse established neuropathy when assessed by nerve conduction, histological integrity and sensorimotor function measurements.

The Company [recently announced](#) encouraging data from the completed Phase 1b portion of its ongoing Phase 1b/2a clinical trial evaluating SON-080 for the treatment of CIPN (the “SB211 study”). The data demonstrated SON-080 to be well-tolerated at both doses, with no evidence of a pro-inflammatory cytokine response. Pain and quality of life survey results suggest the potential for rapid improvement of peripheral neuropathy symptoms and post-dosing durability with both doses, compared to placebo controls. For more information about the SB211 study, visit clinicaltrials.gov and reference identifier [NCT05435742](#).

About Alkem Laboratories Limited:

Alkem Laboratories Limited is a leading Indian pharmaceutical company with a legacy of 50 years in providing high quality medicines to patients. It is the fifth largest pharmaceutical company in the Indian market with a dominant position in the therapy areas of anti-infectives, gastrointestinal, pain management drugs and supplements. It also has a growing portfolio of products in chronic therapies such as diabetes, neurology, cardiology, dermatology and urology. It has 19 state-of-the-art manufacturing facilities and cutting-edge research and development (R&D) centers across India and the US to develop and

manufacture generic formulations, active pharmaceutical ingredients (APIs) and biosimilars. Apart from India, the company has meaningful presence in the US, Latin America, Australia and several Asian countries. "Inspiring Healthier Lives" is at the core of the values and culture of the organisation and reinforces its steadfast commitment to global health improvement. For more information, please visit www.alkemlabs.com and follow us on [LinkedIn](#), [X](#), [Facebook](#), [Instagram](#).

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet is an oncology-focused biotechnology company with a proprietary platform for developing targeted biologic drugs with single or bifunctional action. Known as F_HAB (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. Sonnet's F_HAB was designed to specifically target tumor and lymphatic tissue, with an improved therapeutic window for optimizing the safety and efficacy of immune modulating biologic drugs. F_HAB platform is the foundation of a modular, plug-and-play construct for potentiating a range of large molecule therapeutic classes, including cytokines, peptides, antibodies and vaccines.

Sonnet's lead program, SON-1010, or IL-12-F_HAB, is in development for the treatment of solid tumors and ovarian cancer. SON-1010 is being evaluated in an ongoing Phase 1/2a study through a Material Supply Agreement with Roche in combination with atezolizumab (Tecentriq®) for the treatment of Platinum-Resistant Ovarian Cancer (PROC). The Company is also evaluating its second program, SON-1210, an IL12-F_HAB-IL15 for solid tumors, in collaboration with the Sarcoma Oncology Center to commence an investigator-initiated and funded Phase 1/2a study for the treatment of Pancreatic Cancer.

The Company's SON-080 program is a low dose of rhIL-6 in development for CIPN and DPN. SON-080 demonstrated encouraging results in a Phase 1b/2a clinical trial, being well tolerated with no evidence of a pro-inflammatory cytokine response. Sonnet is currently seeking partnership opportunities to support a Phase 2 trial.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Licensing Agreement, the Company's cash runway, the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve

known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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