February 13, 2025

Sonnet BioTherapeutics Provides Fiscal Year 2025 First Quarter Business and Earnings Update

Completion of SON-1010 (IL12-F_HAB) monotherapy dose escalation in Phase 1 SB101 trial; Stable disease (SD) at four months post-initiation of dosing was seen in 48% evaluable monotherapy patients, and one patient dosed at the MTD, resulting in a partial response (PR)

Continued progress with clinical trials evaluating SON-1010 in combination with Atezolizumab, for Platinum-Resistant Ovarian Cancer (PROC) and in combination with trabectedin in certain advanced soft-tissue sarcomas (STS)

SON-1210 bifunctional Interleukins 12 and 15, on F_HAB platform, in combination with chemotherapy for the treatment of advanced solid tumors and metastatic pancreatic cancer expected to initiate clinical trial with first patient dosed in H1 calendar year 2025

Company has initiated a licensing partnership in India for SON-080 in October 2024 and reorganizes leadership team focused on advancing business development opportunities

PRINCETON, N.J., Feb. 13, 2025 (GLOBE NEWSWIRE) -- Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, today provided its financial results for the three months ended December 31, 2024 and provided a business update.

"We have made strides in our Phase 1 SB101 trial with established clinical benefit including a 45% reduction in tumor size by RECIST criteria indicating a partial response and demonstrating the effectiveness of our F_HAB® platform. This encouraging data with SON-1010 excites us with the ongoing combination trials with Atezolizumab and with the initiation of recruitment for the combination with trabectedin (Yondelis®). Additionally, we continue to bolster our global patent estate and differentiate our plug and play strategy from any competitive technologies that may leverage the beneficial characteristics of binding to human serum albumin," commented Pankaj Mohan, Ph.D., Founder and CEO of Sonnet. "As we look to the remainder of the calendar year, our focus is on our clinical programs and building on our momentum toward meeting potentially catalytic milestones including a number of key clinical data readouts; all of which we believe have the potential to build shareholder value."

Recent Highlights

- Entered into a licensing agreement with Alkem Laboratories Limited ("Alkem") to develop and commercialize SON-080 in India (October 2024).

- Completed SON-1010 (IL12-F_HAB) Monotherapy Dose Escalation in Phase 1 SB101 trial and announced topline safety data (December 2024).
- Closed a registered direct offering and concurrent private placement priced at-the-market under Nasdaq rules for aggregate gross proceeds of $3.9 million (December 2024).
- Announced granting of EU Patent No. EP3583125 B1 covering its F_HAB® platform technology (January 2025).
- Expanded its Phase 1 SB101 clinical study of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors by adding a new patient cohort to evaluate the effect of SON-1010 in combination with trabectedin (January 2025).

Lead Clinical Programs Update

SON-1010*: Targeted Immune Activation Cancer Therapy, Turning 'Cold' Tumors 'Hot', Initially Targeting Solid Tumors and Platinum-Resistant Ovarian Cancer (PROC)*

Phase 1 Trial (SB101 Trial): Advanced Solid Tumors (Monotherapy)

The Company announced the topline safety data from the SB101 trial and completion of dose escalation in December 2024, establishing the MTD as 1200 ng/kg. The final 1200 ng/kg dose-escalation cohort was increased in size to 6 patients to enhance the assessment of PK and PD at the MTD. The SB101 trial employed a 'desensitizing' first dose of 300 ng/kg to take advantage of the known tachyphylaxis with rhIL-12, with the intention of minimizing toxicity and allowing for higher maintenance doses.

Of the 24 patients dosed to date, 17 (71%) had stable disease at the first follow-up CT, 12 of whom were progressing at study entry. 10 of the 21 evaluable patients (48%) remained stable at four months, suggesting SON-1010 clinical benefit, and one of those patients in the highest dose cohort, who has clear cell sarcoma, had a PR with a 45% reduction in tumor size by RESIST criteria. As previously disclosed, one patient in the first dose cohort with endometrial sarcoma who was progressing at study entry had evidence of improvement after 11 months, with smaller tumors and complete resolution of ascites. This patient later progressed at 23 months and started chemotherapy. No dose-limiting toxicities or related serious adverse events (SAE) have occurred to date. The safety and toxicity profile that has developed is typical for a Phase 1 oncology trial, with the majority of adverse events (AEs) being reported as mild. All AEs seen to date have been transient, with no evidence of cytokine release syndrome.

The Company recently announced expansion of its Phase 1 SB101 clinical study of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors to add a new cohort to evaluate the effect of SON-1010 in combination with trabectedin in certain advanced soft-tissue sarcomas (STS), following the successful completion of monotherapy dose escalation. Enrollment in this cohort is underway and is expected to be completed in H1 calendar year 2025. Topline safety data of the combination with trabectedin is expected in H2 calendar year 2025. No new safety concerns have been reported to date.

For more information about the SB101 clinical trial, visitclinicaltrials.gov and reference identifier NCT05352750.

Phase 1b/2a Trial (SB221 Trial): Advanced Solid Tumors and PROC (Combo with Atezolizumab)

The second trial is a global Phase 1b/2a multicenter, dose-escalation and randomized proof-of-concept study to assess the safety, tolerability, PK, PD, and efficacy of SON-1010 administered subcutaneously (SC) in combination with atezolizumab given intravenously (IV) (in collaboration with Genentech, a member of the Roche Group). Enrollment remains ongoing and an update on safety in that trial is expected in Q1 calendar year 2025.

For more information about the SB221 clinical trial, visitclinicaltrials.gov and reference identifier NCT05756907.

SON-1010 Upcoming Milestones

- Phase 1: Solid Tumors (Monotherapy)
  - H1 Calendar Year 2025: Topline Efficacy Data
- Phase 1b/2a: PROC (Combo with Atezolizumab)
  - Q1 Calendar Year 2025: Additional Safety Data
  - H2 Calendar Year 2025: RP2D & Topline Efficacy Data
- Phase 1: STS (Combo with Trabectedin)
  - H2 Calendar Year 2025: Topline Safety Data

SON-1210: *Proprietary, Bifunctional Version of Human Interleukins 12 (IL-12) and 15 (IL-15), Configured Using Sonnet's Fully Human Albumin-Binding (F_HAB) platform, in Combination with Chemotherapy for the Treatment of Advanced Solid Tumors and Metastatic Pancreatic Cancer*

In August 2024, the Company entered into a Master Clinical Collaboration Agreement with the Sarcoma Oncology Center to conduct an investigator-initiated Phase 1/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents including but not limited to NALIRIFOX (the combination of liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin) for the specific treatment of metastatic pancreatic cancer. The NALIRIFOX regimen is U.S. FDA-approved for the treatment of metastatic pancreatic cancer in the front-line and refractory settings. The Company expects to submit the IND for SON-1210 in Q1 calendar year 2025.

SON-1210 Upcoming Milestones

- Q1 Calendar Year 2025: IND Submission
- H1 Calendar Year 2025: 1st Patient Dosed in Investigator-Initiated Phase 1/2a Study

SON-080: *Low dose of rhIL-6 for Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (DPN)*

In October 2024, the Company entered into a licensing agreement with Alkem for the research, development, manufacturing, marketing, and commercialization of its SON-080 molecule for the treatment of DPN in India and the manufacturing, marketing, and commercialization of SON-080 for CIPN and autonomic neuropathy in India. Alkem will

conduct all clinical trials it believes appropriate to obtain regulatory approval of SON-080 in India for the treatment of DPN. Subsequent to the partnership established with Alkem, preparations are being made to support initiation of a Phase 2 clinical trial in DPN, a mechanistically synergistic and larger, high-value indication with unmet medical need.

SON-080 Upcoming Milestone

- H2 Calendar Year 2025: Initiation of Phase 2 Trial

Summary of Financial Results for First Quarter Fiscal Year 2025

For the fiscal first quarter ended December 31, 2024, Sonnet reported a net loss of $3.2 million, or $1.56 per basic and diluted share, compared to a net loss of $1.2 million, or $2.46 per basic and diluted share, for the for the fiscal quarter ended December 31, 2023.

As of December 31, 2024, Sonnet had cash and cash equivalents of $4.9 million.

Company Leadership Reorganization

The Company has promoted Dr. Stephen McAndrew from his role as Senior Vice President, Business Development, to Chief Business Officer to enhance its focus on business development, effective February 17, 2025. Mr. Jay Cross submitted his resignation as Chief Financial Officer, effective February 21, 2025. Mr. Cross will be succeeded by Mr. Donald Griffith, CPA, who has been promoted as the new Chief Financial Officer from his role as Controller, effective February 21, 2025. This update to the Company's leadership team will preserve a continued focus on advancing business development opportunities while remaining vigilant on cost controls.

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 Master Clinical Trial and Supply Agreement, along with ancillary Quality and Safety Agreements, 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

Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (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. In October 2024, Sonnet announced an India license agreement with Alkem Laboratories, Inc. who will assume responsibility for advancing development of the SON-080 program into a Phase 2 study in DPN.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to 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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