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Sonnet BioTherapeutics Announces Progress in Two Phase 1 Dose-Escalation Trials of SON-1010

- ***The SB101 and SB102 studies have together dosed 19 subjects to date***
- ***This early review of safety sets the stage for further dose escalation***
- ***Additional safety and cytokine-specific data are expected during the fourth calendar quarter of 2022***

PRINCETON, NJ / ACCESSWIRE / September 21, 2022 /Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing targeted immunotherapeutic drugs, announced today that initial safety has been formally reviewed in both Phase 1 clinical trials of SON-1010(IL12-FHAB) in adults and that dose escalation is continuing. SB101 is a multiple-dose trial for patients with advanced solid tumors that commenced in April (NCT05352750) and has now started treating the third dose cohort. SB102 is a single-ascending dose trial in healthy volunteers (NCT05408572) that started in July and is dosing the second cohort. Safety Review Committees met to discuss the findings after each cohort, found no safety concerns to prevent moving forward, and approved advancing to the next higher dose levels for both studies.

"We are excited to have now dosed 9 cancer patients in the SB101 study and 10 healthy volunteers in the SB102 study," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "No dose-limiting toxicities have occurred to date using this novel approach to enhance the safety of cytokine-based immunotherapy. Compounds like this have shown great promise in animal models of cancer treatment for decades, yet the developmental progress of IL-12 in human trials has typically been frustrated by toxicity before the therapeutic dose can be reached. By linking an albumin-binding domain to cytokines for targeting tumor tissue and extending the cytokine half-life in the body, we believe our proprietary F_HAB technology may offer the key to inducing a successful local immune response in the tumor microenvironment."

"As the first FHAB technology-derived candidate dosed in patients, the successful start of clinical trials with SON-1010 represents a significant step forward in Sonnet's full-spectrum approach to immunotherapy," said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. "These studies are expected to form the basis for combinations with other types of immunotherapies that could have a synergistic effect on cancer and that we expect will support potential licensing activities."

SON-1010 is a proprietary version of human Interleukin 12 (IL-12), configured using Sonnet's Fully Human Albumin Binding (FHAB™) platform. The FHAB technology targets tumor and lymphatictissue, providing a mechanism for dose sparing and an opportunity to improve the safety and efficacy profile of not only IL-12, but a variety of potent immunomodulators. The pharmacokinetic (PK) and pharmacodynamic (PD) data from these

two trials will provide results needed for the next stage of development using SON-1010.

Interleukin 12 can orchestrate a robust immune response to many cancers and pathogens. Given the types of proteins induced in the tumor microenvironment, such as SPARC and GP60, non-small cell lung cancer, melanoma, head and neck cancer, sarcoma, and several gynecological cancers are particularly relevant for this approach. Despite recent progress in immunotherapy, there continues to be a large unmet medical need.

About the SB101Phase 1 Trial

This first-in-human study is primarily designed to evaluate the safety of multiple ascending doses of SON-1010 in cancer patients and will be conducted at several sites across the United States. While the optimal dose is unknown at this stage, the potential to target tumors, the extended PK mechanism and our preclinical data suggest the therapeutic dose may be lower compared to native human IL-12. The study, utilizing a standard 3+3 oncology design in at least five cohorts, should establish the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) using monthly subcutaneous injections of SON-1010. The primary endpoint explores the safety and tolerability of SON-1010, with key secondary endpoints intended to measure PK, PD, immunogenicity and anti-tumor activity. This study will form the basis for potential combinations with other types of immunotherapies and the future development of bispecific candidates using the FHAB platform.

About the SB102 Phase1 Trial

The SB102 study is designed to robustly evaluate the safety, PK and PD of single ascending doses of SON-1010, using larger groups of healthy volunteers, and is being conducted at a single site in Australia. The study is done in a blinded fashion, comparing a single dose of SON-1010 to placebo utilizing five cohorts. Both PK and PD will be closely followed during dose escalation in this double-blind, placebo-controlled study, along with an assessment of the cellular immune responses at each dose using sophisticated fluorescence activated cell sorting (FACS) analysis. The primary endpoint explores the safety and tolerability of SON-1010, with key secondary endpoints intended to measure PK, PD and immunogenicity.

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet BioTherapeutics is an oncology-focused biotechnology company with a proprietary platform for innovating biologic drugs of single or bispecific action. Known as FHAB (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 FHAB 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. FHAB 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.

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 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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