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Sonnet BioTherapeutics Announces First Patient Dosed in Phase 1 Clinical Trial of SON-1010 for Advanced Solid Tumors

PRINCETON, NJ / ACCESSWIRE / April 13, 2022/ Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing targeted immunotherapeutic drugs, announced today that dosing has been initiated in a Phase 1 clinical trial of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors.

SON-1010 is a proprietary version of human Interleukin 12 (IL-12), configured using Sonnet's Fully Human Albumin Binding (F_HAB™) platform. The F_HAB technology targets tumor and lymphatic tissue, 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.

"We are excited to have dosed the first patient in our trial and to have initiated this novel approach to enhance the safety of cytokine immunotherapy," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "Cytokines have shown great promise in animal models of cancer treatment for several decades, yet the developmental progress in human trials has typically been frustrated by toxicity before the therapeutic dose can be reached. Targeting the tumor by linking an albumin-binding domain, which also extends the cytokine half-life in the body, may be the key to inducing a successful local immune response in the tumor microenvironment."

Interleukin 12 can orchestrate a robust immune response to many cancers and pathogens. Given the types of proteins induced, non-small cell lung cancer, melanoma, head and neck cancer, sarcoma and several gynecological cancers are particularly relevant for this approach.

"As Sonnet's first F_HAB candidate to be dosed in a patient, this SON-1010 milestone represents a significant step forward in our full-spectrum approach to immunotherapy," said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. Dr. Sant Chawla, the Principal Investigator at Sarcoma Oncology Center added, "This Phase 1 clinical trial will carefully assess the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of SON-1010. Despite recent progress in immunotherapy, there continues to be a large unmet medical need in cancer. We are very pleased to be part of this study, as our clinic treats patients with several different types of tumors that could benefit from this approach."

About the SB101 Phase 1 Trial

This first-in-human study is primarily designed to evaluate the safety of multiple ascending doses of SON-1010 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 F_HAB platform.

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 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 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 timing of an IND submission, 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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