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Sonnet BioTherapeutics Announces Clinical Trial of SON-1010 in Healthy Volunteers

- ***Represents Sonnet's second clinical trial with SON-1010***
- ***Study expected to provide important PK and PD data for potential additional indications of interest***
- ***Recruitment initiated with dosing anticipated to begin imminently***

PRINCETON, NJ / ACCESSWIRE / July 21, 2022 /Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing targeted immunotherapeutic drugs, announced today that a second Phase 1 clinical trial of SON-1010(IL12-F_HAB) has been authorized to begin, based on the successful initiation of the first two cohorts in the first-in-human (FIH) dose-escalation trial (SB101) in patients with advanced solid tumors (NCT05352750). This new study (SB102), being conducted in healthy volunteers in Australia, is a single ascending dose-escalation (SAD) trial designed to provide extensive additional pharmacokinetic (PK), pharmacodynamic (PD) and cell response data with SON-1010 (NCT05408572). Importantly, SB102 is expected to inform Sonnet's decisions about pursuing additional indications of interest with SON-1010, as well as augmenting the foundational work underway with the company's bispecific molecules.

SON-1010 is a proprietary version of recombinant human Interleukin 12 (IL-12), configured using the F_HAB technology that targets tumor and lymphatictissue, providing a mechanism for dose sparing due to its extended PK properties. The extension of PK with the F_HAB platform may improve the safety and efficacy profile of IL-12, an effect that can be complemented using a variety of potent immunomodulators that will be linked to the molecule in a bispecific construct in subsequent programs.

"We are excited to dose healthy volunteers in our second clinical study of SON-1010 to further assess the compound's safety, tolerability, PK, and PD " said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. "Despite recent progress in immunotherapy, there continues to be a large unmet medical need in cancer. We believe this study will help simplify development of our F_HAB platform-based bispecific immunotherapy candidates, including SON-1210 and SON-1410, which add IL-15 or IL-18 to the IL12-F_HAB, respectively."

Interleukin-12 has been shown to orchestrate a robust immuneresponse to many cancers and pathogens in patients, as well as in healthy volunteers, but the dosing strategy has been an elusive challenge for over two decades. Given the types of proteins induced,certain types of cancer such as non-small cell lung cancer,melanoma, head and neck cancer, sarcoma, and several gynecological cancers are particularly relevant for this approach.

"Interleukin-12 has been studied in healthy volunteers in the past, so this study is expected to provide a unique opportunity to obtain a more accurate PK assessment using SON-1010 without the background of prior chemotherapy," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "IL-12 has shown great promise in animal models of cancer treatment for decades, yet developmental progress in human trials has typically been hindered by toxicity before the therapeutic dose can be reached. Extending the PK and targeting retention in the tumor microenvironment (TME) through binding to gp60 and SPARC contributes to TME localization of SON-1010. This may be the key to enhancing the therapeutic window and inducing successful immune responses in the TME, as the PD will also be extended to allow better activation of immune cell penetration and replacement of immune inhibitors."

About the SB102 Phase1 Trial

The SB102 studyis primarily designedto evaluate the safety, PK, and PD of single ascending doses of SON-1010, using larger groups of healthy volunteers, and will be conducted at a single site in Australia. While the optimal dose of SON-1010 is currently being investigated, the potential to target tumors, the extended PK mechanism, and our preclinical data allsuggest the therapeutic dose may be lower compared to native human IL-12. The study will be done in a blinded fashion, comparing SON-1010 to placebo utilizing five cohorts. Both PK and PD will be closely followed during dose escalation in this double-blind, placebo-controlled SAD 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 secondaryendpoints intended to measure PK, PD, immunogenicity, and anti-tumor activity. This study is expected to form the basis for potential combinations with other types of immunotherapies that could have a synergistic effect on cancer.

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 Section21E of the Securities ExchangeAct 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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