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Sonnet BioTherapeutics Completes Successful Repeat Dose Study of SON-1010 in Non-Human Primates

- ***The toxicity effects of SON-1010 were well tolerated at doses exceeding levels expected in future human clinical trials, without producing detectable cytokine imbalances***
- ***SON-1010 (IL12-F_HAB) demonstrated an enhanced pharmacokinetic (pK) profile as compared to recombinant IL-12***
- ***Analysis of Interferon-γ levels, a key biomarker of antitumor activity, continue to suggest potent on-target pharmacodynamic effects***
- ***Continuous manufacturing processes intensified for cGMP clinical manufacturing***

PRINCETON, NJ / ACCESSWIRE / February 1, 2021 /Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing targeted immunotherapeutic drugs, announced today that it has successfully completed a non-human primate (NHP) repeat-dose study of SON-1010, a proprietary fully human Interleukin 12 (IL-12) therapeutic candidate configured using Sonnet's Fully Human Albumin Binding (F_HAB) platform. The F_HAB technology targets tumor tissue, providing a mechanism for dose sparing and an opportunity to improve the safety and efficacy profile of immunomodulatory cytokines.

The objectives of the study were to evaluate the toxicity of SON-1010 in a repeat dose regimen at two different doses and to gather critical data for the design of further IND-enabling safety and toxicity studies. The study included both intravenous and subcutaneous routes of administration with a total of two doses given 14 days apart. The high dosage rate utilized in this study was greater than 50 times the anticipated clinical level of exposure to patients.

Study results included:

- Repeat dosing by intravenous and subcutaneous routes of administration were tolerated at both dose levels examined. As is typically observed with IL-12 administration, the white blood cell count dropped, and liver enzymes (ALT and AST) were elevated. These were transient effects that returned to baseline within 7 days following the second dose.
- SON-1010-related changes in the physiological observations, body weight, pathology, cytokines and immunophenotyping were seen, all of which were consistent with those on-target effects previously observed in single dose studies.
- A significant increase in Interferon-γ levels, a key pleiotropic cytokine associated with anti-tumor activity, was observed following the initial dose of SON-1010 with lower Interferon-γ levels observed following the second dose. This trend follows the

published data from other studies of IL-12 in both humans and NHPs.
- Pharmacokinetic analysis indicated a mean serum half-life of approximately 40 hours for animals administered SON-1010 via subcutaneous injection. This is consistent with data from the previously conducted dose escalation phase of the study, which demonstrates a substantial improvement in half-life compared to the 13-19-hour half-life of naked, recombinant human IL-12.

Pankaj Mohan, Ph.D., Sonnet founder and CEO, commented, "Taken in combination with our recent single dose toxicology results, these repeat dose data further reinforce our confidence in the SON-1010 safety and efficacy profile as we look forward to initiating the Phase 1 clinical development program later this year."

Sonnet used these data to inform the design of the ongoing GLP toxicity studies in preparation for IND submission. Additionally, the Company has developed a, continuous manufacturing platform consisting of an industry standard mammalian cell (Chinese Hamster Ovary or CHO) host cell line coupled with an intensified perfusion process that allows for rapid scale-up and commercial manufacturing, using state-of-the-art processes and technologies. The mammalian cell culture system enables glycosylation, thereby reducing the risk of immunogenicity.

Susan Dexter, Sonnet's Chief Technology Officer added, "We have established an intensified, continuous manufacturing process, as compared with an industry standard fed batch process, to enhance productivity and improve the yield of difficult-to-express cytokines. We believe that the ability to manufacture SON-1010 as a single genetic sequence will enable scale up and optimize product quality. A lyophilization formulation provides stability and refrigerated cold chain simplicity."

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 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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