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Sonnet BioTherapeutics Announces the Completion of a Successful Non-Human Primate Study of SON-1010

- ***Compared to recombinant human IL-12, SON-1010 demonstrated an enhanced pharmacokinetic (PK) profile that was similar to IgG antibodies***
- ***SON-1010 continues to be well tolerated at doses far exceeding levels expected in potential future clinical trials, without producing detectable cytokine imbalances***
- ***Analysis of Interferon-γ levels, a key biomarker of antitumor activity, suggest potent on-target pharmacodynamic (PD) effects***

PRINCETON, NJ / ACCESSWIRE / November 30, 2020 /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) 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. Sonnet's 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 IL-12, as well as other immunomodulators. The objectives of this dose range-finding study were twofold: to confirm the enhanced PK profile of SON-1010 in comparison to recombinant human IL-12 (demonstrated previously in a humanized mouse model), and to perform a dose escalation to inform and de-risk the design of follow-on NHP studies needed for the SON-1010 IND filing with the FDA.

Pankaj Mohan, Ph.D., Founder and CEO, commented, "We are excited by these data that indicate a potentially broad therapeutic window for SON-1010, our proprietary F_HAB-Interleukin 12 drug candidate. IL-12 is widely viewed as holding promise as a therapeutic in the oncology setting, however, this application has been limited by its toxicity and pharmacokinetic profile. We believe today's announcement represents another important step forward towards unlocking the therapeutic potential of IL-12, as well as other compounds in our pipeline."

Dr. Hossein Borghaei, D.O., M.S., a member of Sonnet's Scientific Advisory Board and Chief of Thoracic Medical Oncology at Fox Chase Cancer Center, commented, "The encouraging results from this non-human primate study suggest that the IL12-F_HAB may be well tolerated in humans. Along with further toxicology studies, we believe this work sets the table for future potential clinical trials in lung cancer and head and neck cancers."

The data from this study indicate that in healthy cynomolgus macaques of both sexes, a single dose of SON-1010 is well tolerated at dosage levels greater than 50 times the anticipated exposure in human clinical trials. Additionally, SON-1010 elicited a prolonged

and potent on-target PD effect as measured by, Interferon-γ (IFN-γ), a key biomarker of antitumor activity. On-target and transient changes in clinical chemistry and pathology parameters were observed, but resolved completely within 14 to 21 days post-dosing. Signs of cytokine imbalance, or uncontrolled increase of pro-inflammatory cytokines, including TNF-α, IL-1β, and IL-6 were notably absent from all dose levels tested in the study. Pharmacokinetic analysis of serum samples from the study animals indicated a mean half-life of 40.0 (±6.9) hours for subcutaneous dose routes and 27.45 (±2.8) hours for intravenous dose routes. These results build on those from a prior study using the B16F10 mouse model of melanoma, where the mouse version of SON-1010 showed a 20-fold reduction in the dosage required to achieve a similar therapeutic effect compared to mouse IL-12. Taken together, the observed extended half-life, improved therapeutic window and reduced dosing requirement, made possible by Sonnet's F_HAB technology, represent key advantages of SON-1010 as a potential immune oncology therapeutic.

John Cini, Ph.D., Co-founder and Chief Scientific Officer, added, "We designed our F_HAB technology to leverage the therapeutic properties of otherwise toxic immune modulating compounds, by optimizing their tolerability and adding a targeted delivery mechanism. This study is an important milestone for SON-1010, and we believe further validates the fundamental strengths of our drug development platform."

Results from the second phase of this NHP study, which includes a repeat dose regimen in healthy cynomolgus macaques, are expected in the coming weeks. Collectively, these data will be applied to advance SON-1010 to potential first-in-human Phase I clinical testing in patients with solid tumors, specifically lung cancer and head and neck cancers, with an IND submission anticipated during the second half of 2021.

About Sonnet BioTherapeutics Holdings, Inc.

Founded in 2011, 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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