September 1, 2020

Sonnet Announces New Preclinical Data for SON-1010 (Interleukin 12-F(H)AB)

- ***Positive SCID mouse data further support the preclinical safety and dosing profile of SON-1010 for oncology applications***
- ***No evidence of cytokine storm was observed***
- ***Company is on track to submit an IND in 2021***

PRINCETON, NJ / ACCESSWIRE / September 1, 2020 /Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing innovative targeted biologic drugs, announced today that it has successfully completed a preclinical Severe Combined Immunodeficient (SCID) mouse study of its fully human Interleukin 12 (IL-12) candidate, SON-1010, a F_HAB-derived molecule comprising Interleukin 12 and Sonnet's Fully Human Albumin Binding (F_HAB) technology.

This humanized mouse study further evaluated the pharmacokinetics (PK) and tolerated dose range for oncology applications. As with the Company's previous studies in non-humanized mice that compared a mouse IL-12 albumin-bound construct with naked/unbound mouse IL-12, SON-1010 continues to display similar levels of significantly enhanced PK. The company observed that, regardless of PBMC (human peripheral blood mononuclear cells) donor, Interferon Gamma (IFN-γ) levels responded in a dose dependent manner. IFN-γ is a key biomarker that leads to activation of the immune system. Furthermore, at all dose levels, no toxicity and no evidence of adverse immune reactions associated with cytokine storm were observed.

The study included a single dose at multiple concentrations in both intravenous and subcutaneous modes of administration. Animals were injected with pre-screened PBMCs, and then serum samples were analyzed at various timepoints. Both circulating IL12-F_HAB and key cytokine biomarkers were evaluated during the assessment of PK and safety. Body weight and animal health measurements were also performed at regular intervals. No evidence of body weight changes or cytokine imbalances were seen, regardless of dose or route of administration. Cytokines measured included, IL-1β, IL-2, IL-4, IL6, IL-8, IL-10 and TNF-α, and were similar to that of the vehicle control (phosphate buffered saline).

Pankaj Mohan, Ph.D., Founder and CEO, commented, "IL-12 is a potent immunomodulatory cytokine that is receiving heightened attention for its anti-cancer activity and we believe these compelling new data, in addition to the data we have already collected, suggest that SON-1010 represents a potentially safe and effective IL-12 therapeutic compound. With a fully human candidate in hand, we have provided important validation of our platform technology, and we remain laser-focused on initiating first-in human clinical studies during the second half of 2021."

John Cini, Ph.D., Co-Founder and CSO added, "These SCID mouse data are very

encouraging and are consistent with our expectations, based on the body of proof-of-concept data we have generated to date. We are working to quickly move into nonhuman primate studies to further evaluate drug toxicity, in preparation for our IND submission in 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. 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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SOURCE: Sonnet BioTherapeutics, Inc.

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