May 10, 2021

Sonnet BioTherapeutics Completes Successful GLP Repeat Dose Toxicology Study of IL12-FHAB (SON-1010) in Non-Human Primates (NHP)

- ***The No Observed Adverse Event Level (NOAEL) following repeated administration was more than 50 times the anticipated equivalent human clinical dose in NHP with no evidence of cytokine release syndrome.***
- ***Pharmacokinetic (PK) analysis of serum samples confirmed an enhanced profile of IL12-F_HAB over recombinant human IL-12, with a half-life around 40 hours in NHP.***
- ***A significant increase in Interferon-γ, a key pleiotropic cytokine associated with anti-tumor mechanisms, was observed following dosing with IL12-F_HAB.***

PRINCETON, NJ / ACCESSWIRE / May 10, 2021 / Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a biopharmaceutical company developing innovative targeted biologic drugs, announced today that it has completed a successful preclinical nonhuman primate (NHP) GLP repeat-dose study of SON-1010, a proprietary version of 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.

The objectives of the study were to evaluate the toxicity of SON-1010 in NHP using a subcutaneous, repeat-dose regimen at three different dose levels versus untreated controls and to evaluate the potential reversibility of any adverse findings.

Pankaj Mohan, Ph.D., Sonnet founder and CEO, commented, "This GLP study was an important milestone to support an IND with the FDA. SON-1010 has now accrued, along with previous non-GLP data, a significant NHP toxicology dataset. The NHP data continues to demonstrate that SON-1010 appears to be safe and is eliciting the expected immune responses that we believe could position this as an effective treatment for multiple types of cancer."

Study results included:

- The No Observed Adverse Event Level (NOAEL) following repeated administration was more than 50 times the anticipated equivalent human clinical dose in NHP with no evidence of cytokine release syndrome.
- Pharmacokinetic (PK) analysis of serum samples confirmed an enhanced profile of IL12-F_HAB over recombinant human IL-12, with a half-life around 40 hours in NHP.

- A significant increase in Interferon-γ, a key pleiotropic cytokine associated with anti-tumor mechanisms, was observed following dosing with IL12-F_HAB.
- SON-1010 related changes in clinical observations, body weight, clinical pathology, cytokines, and immunophenotyping were seen, all of which were consistent with on-target effects previously observed in nonhuman primates.
- By Day 38 all study subjects recovered to baseline (pre-study) values.
- Repeat dosing administration was tolerated at all dose levels examined.

Richard T. Kenney, M.D., Chief Medical Officer, commented, "Interleukin-12 is a key immunomodulator that bridges innate and adaptive immunity, but showed toxicity in the first human trials over two decades ago. Careful subcutaneous administration of IL-12 has been shown to be a safe dosing approach, even in healthy volunteers. Given that IL12-F_HAB has an extended half-life, tolerable doses can be given at longer dosing intervals. SON-1010 has IL-12 attached to a proprietary fully human albumin binding construct, which provides the longer half-life and targeting capability that may be needed to treat tumors. The NHP data suggests that our candidate will be well tolerated. We believe that this novel approach can lead to an effective treatment regimen for multiple types of cancer".

Sonnet's cell-based manufacturing platform coupled with an intensified perfusion process using state-of-the-art technologies allows rapid scale-up for future commercial manufacturing. Our mammalian cell culture system enables glycosylation, thereby reducing the risk of inducing immunogenicity with IL12-F_HAB. We are on track for providing GMP material for initiation of the clinical trial in 2H 2021.

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.

Sonnet Biotherapeutics Investor Contact

Alan Lada
Solebury Trout
617-221-8006
alada@soleburytrout.com

SOURCE: Sonnet BioTherapeutics, Inc.

View source version on accesswire.com:
https://www.accesswire.com/645973/Sonnet-BioTherapeutics-Completes-Successful-GLP-Repeat-Dose-Toxicology-Study-of-IL12-FHAB-SON-1010-in-Non-Human-Primates-NHP