January 25, 2021

Sonnet BioTherapeutics Announces the Successful Completion of a Non-human Primate Toxicology Study of SON-080

- ***No adverse effects observed at all doses tested***
- ***Using the results of this study, combined with previously compiled clinical safety data, the Company intends to commence evaluation of human equivalent doses for initiating pilot clinical efficacy studies***
- ***An IND submission for Chemotherapy Induced Peripheral Neuropathy is expected in the second half of 2021***

PRINCETON, NJ / ACCESSWIRE / January 25, 2021 / Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing targeted immunotherapeutic drugs, announced today that Sonnet BioTherapeutics CH SA ("Sonnet CH"), a wholly owned subsidiary of Sonnet headquartered in Switzerland, has successfully completed a multiple dose non-human primate (NHP) study of SON-080 (low-dose recombinant fully human Interleukin 6, or IL-6). The toxicology study demonstrated a wide safety margin with no adverse effects observed in male or female cynomolgus monkeys at the doses tested. As a next step, the Company intends to determine human equivalent doses. Sonnet CH is planning to initiate pilot scale efficacy clinical trials during the second half of 2021 for Chemotherapy Induced Peripheral Neuropathy (CIPN), followed by Diabetic Peripheral Neuropathy (DPN).

Pankaj Mohan, Ph.D., Sonnet founder and CEO, commented, "These toxicology data represent an important step forward toward unlocking the potential of low-dose IL-6 for the treatment of neuropathies, a family of conditions affecting millions of cancer and diabetes patients around the world. We believe the potential patient benefit could be significant, as these conditions lack disease modifying therapeutic options."

Highlights from the NHP toxicology study:

- Animals were subcutaneously administered SON-080 three times per week at doses of 1, 3 and 30 µg/kg compared to placebo, over a 13-week period.
- The placebo and high dose groups were maintained for an additional three weeks for further observation.
- Health parameters, including blood pressure, respiratory readouts, food consumption and weight, were monitored throughout the study.
- Blood samples were collected to measure the levels of circulating SON-080 during the study, in order to measure blood exposure to the drug, detect the potential presence of anti-drug antibodies (ADA) and to conduct blood chemistry analysis.
- Histopathological analysis was performed on the animals' organs at the end of the experiment.

Results

- IL-6 subcutaneously administered at the three dose levels tested (mean actual doses of 0.8, 2.4 and 24.9 µg/kg estimated on the basis of the repeated formulation analysis) induced no adverse effects in the male or female cynomolgus monkey.
- No mortality occurred in animals dosed at the three dose levels tested.
- No test item-related clinical signs, nor changes in body weight, food consumption, ophthalmological examination and cardiovascular parameters were observed.
- No test item-related changes in clinical chemistry parameters at 1 µg/kg in both sexes and at 3 µg/kg in females were observed.
- Test item-related changes in clinical chemistry parameters were observed in males at 3 and 30 µg/kg and in females at 30 µg/kg, in Week 4 and/or Week 13. Given their low magnitude and in the absence of associated signs of toxicity, these changes were considered non adverse.
- No test item-related changes in urinary parameters were observed.
- Histopathology examination revealed minor inflammatory changes at the injection sites in both sexes at all dose levels tested, which were considered non adverse given their incidence and severity.
- Based on these experimental results, we believe it is possible to calculate human dose equivalents, considering a large safety margin of approximately 1 µg/kg, which will be the upper limit of the dose range to be applied in the neuropathy clinical trials.

Gael Hedou, Ph.D., COO of Sonnet Biotherapeutics CH SA, commented, "These NHP tox data are another important building block supporting our confidence in SON-080 as a therapeutic candidate for CIPN and DPN. From my own years of work on SON-080, and the decades of study accumulated in preclinical species and in humans, I believe that low-dose IL-6 holds promise for fundamentally improving the lives of patients who suffer from these debilitating diseases."

The SON-080 molecule has undergone significant preclinical and clinical testing by licensor, Merck KGaA. These prior studies evaluated IL-6's efficacy in cancer patients undergoing chemotherapy who suffered from thrombocytopenia. Although these initial evaluations did not meet the clinical efficacy hurdle set for thrombocytopenia, results from preclinical models of neuropathy suggest that low doses of SON-080 might be sufficient to reverse the neurological damage and clinical symptoms associated with these indications.

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 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 letter of intent and the potential partnership with New Life, 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. There can be no assurance that a definitive agreement will be executed by the parties. 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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