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Sonnet BioTherapeutics Announces Clinical Trial of SON-080 in Patients with Persistent Chemotherapy-Induced Peripheral Neuropathy

- ***Sonnet's first clinical trial with SON-080 is a Phase 1b/2a double-blind, randomized controlled trial***
- ***This trial is expected to provide safety data compared to previous IL-6 products, along with preliminary efficacy***
- ***Recruitment initiated with dosing anticipated to begin imminently***

PRINCETON, NJ / ACCESSWIRE / July 22, 2022 /Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing targeted immunotherapeutic drugs, announced today that a Phase 1b/2a clinical trial of SON-080 has been authorized to begin. This new study (SB211) will be conducted at multiple sites in Australia in patients with persistent chemotherapy-induced peripheral neuropathy (CIPN). Many drugs cause peripheral nerve damage and patients with CIPN experience discomfort that can culminate in unbearable pain, which may be a reason to limit chemotherapeutic treatment of the underlying cancer, thereby jeopardizing the chances of the patient's survival. Once established, neuropathy often causes pain, as well as non-pain-related symptoms that can deteriorate the patient's quality of life. This study is a Phase 1b/2a double-blind, randomized controlled trial that is designed to demonstrate safety in patients with CIPN for at least 3 months, compared with prior efforts to develop IL-6 at higher doses for other indications, to give additional pharmacokinetic (PK) and pharmacodynamic (PD) data at these doses and to show a preliminary indication of efficacy (NCT05435742).

SON-080 is a proprietary version of recombinant human Interleukin-6 (rhIL-6) that has a sequence identical to the native molecule. As a pleiotropic cytokine, IL-6 participates in several physiological processes including, the innate immune response. The complex biology of IL-6 involves two distinct regulation paths with different consequences. High and prolonged levels of IL-6 potently induce acute-phase proteins, several complement system proteins, and the coagulation cascade and are associated with pathological inflammatory states. In contrast, when native IL-6 is produced at lower levels following moderate exercise or circadian rhythms it can reduce inflammation, improve tissue healing, and help with glucose homeostasis, among other effects. In addition, low dose rhIL-6 has the potential to stop nerve degeneration and is predicted to stimulate nerve regrowth to re-establish normal sensations, thereby reducing pain and normalizing some of the physiological conditions that have deteriorated due to nerve degeneration. The doses proposed for the CIPN indication should result in about the same serum levels of IL-6 that are associated with the physiologic response to moderate exercise.

"We are excited to dose patients with persistent CIPN in our first clinical study of SON-080,"

said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. "Serono International laid the groundwork for safety with the prior version of IL-6 and showed evidence of nerve regeneration in animal models of CIPN. Should our revised product confirm safety, we will initiate a larger Phase 2 study to address diabetic peripheral neuropathy (DPN), which represents an even larger unmet need in pain management."

Development of CIPN is one of the most common adverse effects of chemotherapy and in many cases it is the major dose-limiting toxicity. Neuropathic symptoms are predominantly sensory or sensory-motor in nature, accompanied in some cases by dysfunction of the autonomic nervous system. There are currently no treatments available for the prevention or cure of CIPN; current management includes dose modification or discontinuation of the chemotherapeutic agent, while attempting symptomatic control of pain with analgesics and pain modulators. Preclinical studies with rhIL-6 led to significant improvement in motor and sensory nerve conduction velocity, motor latency, sensory nerve action potentials, and nerve histology.

"Interleukin-6 has been extensively studied in cancer patients in the past, so the use of SON-080 in CIPN is expected to provide similar safety, PK, and PD results at low doses," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "The preclinical models showing improvements in nerve function and histology suggest possible benefits in humans with CIPN. This approach is a unique way to actually treat the underlying causes of CIPN rather than trying to mask the symptoms."

Previous preparations of rhIL-6 have been administered to oncology patients, patients prior to and following autologous bone marrow transplantation for non-hematologic malignancies, and patients suffering from Fanconi's anemia or idiopathic aplastic anemia. Recombinant hIL-6 has been administered to patients with Type 2 diabetes or fibromyalgia, as well as to healthy volunteers.

About the SB211 Phase1b/2a Trial

The SB211 study is primarily designed to evaluate the safety, PK, PD, and initial efficacy of two dose levels of SON-080 that is self-administered 3 times a week subcutaneously, in patients with CIPN lasting at least 3 months after chemotherapy, conducted at multiple sites in Australia. The study will be done in a blinded fashion, comparing SON-080 to placebo. The primary endpoint explores the safety and tolerability of SON-080, with key secondary endpoints intended to measure PK, PD, and immunogenicity. Preliminary efficacy will be explored using standardized pain questionnaires over the course of the trial.

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 Section21E 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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