June 20, 2023

Sonnet BioTherapeutics Announces Regulatory Approval for Initiation of a Clinical Trial of SON-1010 Combined with Atezolizumab

- ***Clinical trial was approved by the Bellberry Human Research Ethics Committee (HREC) in Australia***
- ***The combination of Sonnet's SON-1010 and Roche's atezolizumab (Tecentriq®) will be evaluated for the treatment of platinum-resistant ovarian cancer***
- ***Recruitment is being initiated with dosing anticipated to begin imminently***

PRINCETON, NJ / ACCESSWIRE / June 20, 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-1010 (IL12-F_HAB) in combination with Roche's anti-PD-L1 checkpoint inhibitor, atezolizumab (Tecentriq®), has been approved to begin in Australia. The approval by the Bellberry HREC was based on scientific and ethical review of trial documentation, which included the successful completion of a study of SON-1010 monotherapy (SB102) in healthy volunteers (NCT05408572) and demonstration of continued safety in the first-in-human (FIH) dose-escalation trial in cancer (SB101). The latter is a study of patients with advanced solid tumors that will now focus on platinum-resistant ovarian cancer (PROC) in the USA (NCT05352750). The new study (SB221), which will also focus on the treatment of PROC (NCT05756907), consists of a dose-escalation phase in Part 1 and a randomized comparison of the combination versus SON-1010 monotherapy or the standard of care (SOC) in Part 2. Importantly, SB221 is expected to show proof-of-concept (POC) with SON-1010 for PROC, as well as augmenting the foundational work underway with the Sonnet bifunctional molecules, SON-1210 and SON-1410.

"Atezolizumab and other checkpoint inhibitors have shown preliminary clinical activity in patients with ovarian cancer. The extended PK of SON-1010, along with its ability to target and be retained within the tumor microenvironment (TME) of solid tumors, creates an excellent opportunity for synergistic activity in combination with other therapies", said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "Ovarian cancer has a high expression of proteins that bind albumin, so the anticipated induction of immune responses can make this relatively ‘cold' tumor immunologically ‘hot'. This may be the key to enhancing the therapeutic window and inducing successful immune responses in the TME, as the PD will also be extended to allow better activation of immune cell penetration and replacement of immune inhibitors."

SON-1010 is a proprietary version of recombinant human Interleukin 12 (IL-12), configured using the F_HAB technology that targets tumor and lymphatic tissue, that provides a

mechanism for dose sparing due to its extended PK properties. The extension of PK with the F_HAB platform may improve the safety and efficacy profile of IL-12, an effect that can be complemented using a variety of potent immunomodulators that will be linked to the molecule in a bispecific construct in subsequent programs. Atezolizumab is an immune checkpoint inhibitor approved for the treatment of some of the most aggressive and difficult-to-treat forms of cancer. The characteristics of ovarian cancer present a unique opportunity to assess the combination of these two agents in an indication that persists as a large unmet medical need.

Interleukin-12 has been shown to orchestrate a robust immuneresponse to many cancers and pathogens in patients, as well as in healthy volunteers, but the dosing strategy has been an elusive challenge for over two decades. Sonnet's initial Phase 1 studies with SON-1010 have provided many clues to help improve the dose levels and intervals. Given the types of proteinsinduced, gynecological cancers are particularly relevant for this approach.

"We are excited to study the combination of SON-1010, our best-in-class IL12-F_HAB immune-enhancer candidate, with atezolizumab in platinum-resistant ovarian cancer to further assess our compound's safety, tolerability, PK, and PD", said Pankaj Mohan, Ph.D., Sonnet's Founder and Chief Executive Officer. "Ovarian cancer patients who are resistant to platinum compounds have very few options for successful treatment. Despite recent progress in immunotherapy, there continues to be a large unmet medical need in ovarian cancer. The combination of SON-1010 with atezolizumab provides a novel alternative that may improve the rate of response in this difficult life-threatening disease."

About the SB221 Phase1b/2a Trial

SB221 is a global Phase 1b/2a multicenter, dose-escalation and randomized proof-of-concept study to assess the safety, tolerability, PK, PD, and efficacy of SON-1010 administered subcutaneously (SC), either alone or in combination with atezolizumab given intravenously (IV). The study is designed in Part 1 to rapidly establish the maximum tolerated dose (MTD) of the combination, starting in patients with advanced solid tumors and moving to PROC in small dose-escalation groups, then to expand the dataset at the recommended Phase 2 dose (RP2D) to show the likelihood of efficacy in PROC using a standard 2-stage design. This would be followed in Part 2 by an assessment in patients with PROC of the potential for improved efficacy of the combination over SON-1010 alone or the standard of care. Both Sonnet and Roche look forward to this collaboration as an opportunity to improve outcomes for patients with ovarian cancer.

About SonnetBioTherapeutics 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 ExchangeAct 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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SOURCE: Sonnet BioTherapeutics, Inc.

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