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Sonnet BioTherapeutics Announces FDA Acceptance of the Company's IND for the SB221 Clinical Trial of SON-1010 Combined with Atezolizumab in the US

- ***An IND was required to conduct the SB221 study of platinum-resistant ovarian cancer (PROC) with the combination of Sonnet's SON-1010 and Roche's atezolizumab (Tecentriq®) in the US***
- ***As part of the overall design of the program, the clinical trial was initiated at several sites in Australia after HREC regulatory approval and TGA notification***
- ***The IND acceptance by FDA allows for a global clinical effort, with the possibility for more rapid recruitment through the addition of US trial sites***

PRINCETON, NJ / ACCESSWIRE / August 16, 2023 /Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a clinical-stage company developing targeted immunotherapeutic drugs, announced today that the IND for SB221 (NCT05756907), the Phase 1b/2a clinical trial of SON-1010(IL12-F_HAB) in combination with Roche's anti-PD-L1 checkpoint inhibitor, atezolizumab, has been accepted, and the study can begin in the US for the treatment of PROC. The trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose (MTD) of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose (RP2D). Part 2 of the study will then investigate SON-1010 monotherapy, its use in combination with atezolizumab, or the standard of care (SOC) for PROC in a randomized comparison to show proof-of-concept (POC).

"We are pleased that FDA has authorized moving forward with this trial in the US after reviewing the sequential approach that was designed for this indication," said Pankaj Mohan, Ph.D., Sonnet's Founder and Chief Executive Officer. "We will also be implementing a more easily stored, lyophilized form of SON-1010 in this US trial, which was also used in the SB102 trial in Australia in healthy volunteers. This is an important advancement, after showing comparability with the liquid formulation that is currently being studied in the SB101 first-in-human (FIH) US dose-escalation trial in cancer."

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 pharmacokinetic (PK) properties. The extension of PK observed with the F_HAB technology may improve the safety and efficacy profile of IL-12, which may be complemented further with a variety of potent immuno-modulators linked to the molecule in a bispecific construct. 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.

"Following FDA's review, an important step in establishing further acceptance of the clinical design for SB221, we believe that adding the US sites for this trial will help accelerate the recruitment rate," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "Although the various treatment options for ovarian cancer have improved over the past decade, response rates continue to be disappointing with little progress in overall survival. We have demonstrated an extended PK for SON-1010, along with an ability to target and accumulate within the solid tumor microenvironment (TME). This presents an excellent opportunity to display synergistic activity in combination with atezolizumab, particularly in tumors that avidly bind albumin, like ovarian cancer. We are excited to expand the study to the US, with the goal of enhancing study enrollment and advancing to the POC effort in Part 2 sooner."

About the SB221 Phase1b/2a Trial

SB221 is a global Phase 1b/2a multicenter, dose-escalation and randomized POC 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 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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