

August 30, 2021



Sonnet Announces Successful Completion of the Discovery Phase for Its Next Preclinical Pipeline Candidate (SON-1410)

- ***SON-1410 (IL18-F_HAB-IL12), a bispecific combination of Interleukins 18 and 12, was selected based on data generated in a mouse melanoma study comparing three bispecific constructs***
- ***Selection of the asset was performed with input from Sonnet's Scientific Advisory Board***
- ***An IND submission for SON-1410 is anticipated during the second half of 2022***

PRINCETON, NJ / ACCESSWIRE / August 30, 2021 / Sonnet BioTherapeutics Holdings, Inc., (NASDAQ:SONN) a biopharmaceutical company developing innovative targeted biologic drugs, announced today that it has selected a novel development candidate after completing comparative studies in a mouse melanoma model. The candidate represents Sonnet's second bispecific compound integrating Interleukin 12 (IL-12) with the company's Fully Human Albumin Binding (F_HAB) platform. The target indications for SON-1410 will be melanoma and renal cancers.

Pankaj Mohan, Ph.D., Sonnet founder and CEO, commented, "Following our recently completed \$30 million financing, we are excited to have identified this latest bispecific candidate, which is scheduled to enter the next stages of its development during the fourth quarter of 2021, with the objective of filing an IND in the second half of 2022. Our Scientific Advisory Board is very encouraged by these latest data and by the opportunity to further expand our work with IL-18 and IL-12, as we continue the buildout of our immuno-oncology pipeline."

IL18-F_HAB-IL12 showed statistically significant tumor size reduction in a mouse melanoma study compared with the placebo, as well as a dose response. The data demonstrated:

Test Article	Day 0, Single Dose Tumor @ 100 mm ³	Day 8 Tumor Volume (mm ³ +/- SEM), N=8	Day 8 Percentage Tumor Shrinkage
Placebo	NA	1747 +/- 301	-
IL18-F _H AB-IL12	1 µg	918 +/- 130	47%

IL18-F _H AB-IL12	5 µg	619 +/- 141	65%
-----------------------------	------	-------------	-----

A separate mouse study was also performed comparing the selected version of IL18-F_HAB-IL12 with two other candidates, GMCSF-F_HAB-IL18 and GMCSF-F_HAB-IL12. The comparison data indicated significantly greater reduction in tumor volume, along with higher Interferon Gamma levels and immune cell responses (NK, NKT, Th1, and cytotoxic CD8 T cells) using IL18-F_HAB-IL12, compared with GMCSF-F_HAB-IL12 or GMCSF-F_HAB-IL18. Based on this study, SON-1410 (IL18-F_HAB-IL12) will replace SON-2014 (GMCSF-F_HAB-IL18) as a development program.

The data was reviewed by Sonnet's Scientific Advisory Board, composed of leading oncology specialists from MD Anderson Cancer Center, Fox Chase Cancer Center, UMDNJ-Robert Wood Johnson Medical School/Cancer Institute of New Jersey, and Moffitt Cancer Center, Tampa, Florida.

Sonnet Chief Scientific Officer and Co-Founder, John K. Cini, Ph.D., said, "I am excited about IL18-F_HAB-IL12 becoming our second bispecific candidate that utilizes IL-12. There appears to be synergy between these interleukins, as IL-18 upregulates the IL-12 receptor and IL-12 upregulates the IL-18 receptor. IL-18 also appears to increase chemokines CXCL9 and CXCL10. SON-1410 has the potential to make a cold tumor immunologically hot. Used with a checkpoint inhibitor, SON-1410 could synergistically enhance clinical efficacy. Bispecific assets on the F_HAB platform offer targeted delivery to tumors and an extended half-life, potentially improving the therapeutic index for safety and tolerability with enhanced efficacy."

Richard T. Kenney, M.D., Sonnet's Chief Medical Officer, added, "The decision to move the SON-1410 construct forward is an important one for Sonnet, as we continue our search for novel, bispecific combinations with profound anticancer properties. IL-18 is a member of the IL-1 superfamily of cytokines that activates Th1 cells when combined with IL-12, as well as stimulating natural killer (NK) cells. The mouse data we generated demonstrate that SON-1410 represents a molecule that may harness IL-18 as a potentially effective therapeutic tool for oncologists."

Sonnet is initiating the manufacturing process for SON-1410 with cell line and process development, which will be followed by manufacturing for a toxicology study, with the intention of filing an IND during the second half of 2022.

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 F_HAB (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 F_HAB 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. F_HAB 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 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 the Company operates 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 the Company's 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

Michael V. Morabito, Ph.D.
Solebury Trout
917-936-8430
mmorabito@soleburytrout.com

SOURCE: Sonnet BioTherapeutics, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/662006/Sonnet-Announces-Successful-Completion-of-the-Discovery-Phase-for-Its-Next-Preclinical-Pipeline-Candidate-SON-1410>