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Sonnet BioTherapeutics Announces FDA Clearance of Its IND for SON-1010 for the Treatment of Advanced Solid Tumors

- ***Represents Sonnet's first IND cleared***
- ***Phase 1 trial initiation expected in 2Q22***

PRINCETON, NJ / ACCESSWIRE / March 16, 2022 /Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) ("Sonnet" or the "Company"), a biopharmaceutical company developing innovative targeted biologic drugs, announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for SON-1010, a proprietary version of Interleukin 12 (IL-12) configured using Sonnet's Fully Human Albumin Binding (F_HAB™) technology. This will allow Sonnet to initiate its First-in-Human Phase 1 trial in adult oncology patients in the second quarter of 2022.

"The FDA's acceptance of the IND for SON-1010 is an important milestone in the development of our lead F_HAB asset, signifying the evolution of Sonnet into a clinical biopharmaceutical company," said Pankaj Mohan, Ph.D., Founder and Chief Executive Officer. "We are excited about the progress we have made with our F_HAB platform, which we believe will set the stage for improved efficacy of monospecific and bispecific cytokines, each differentiated by tumor targeting and retention in the tumor microenvironment."

The planned Phase 1 trial will be a multiple ascending dose study designed to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of SON-1010 in adult patients with advanced solid tumors. "We have worked hard to establish a dose range for this extended PK form of IL-12 that can be tested safely and may provide an enhanced therapeutic index," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "The goal of this strategy is to carefully adjust the body's cells and cytokines to enhance the innate immune response to tumors." The study, utilizing a standard 3+3 oncology design in at least 5 cohorts, will establish the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) using monthly subcutaneous injections of SON-1010. The primary endpoint will assess the safety and tolerability of SON-1010, with key secondary endpoints planned to measure PK, PD, immunogenicity, and anti-tumor activity.

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. 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 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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