## Sona Nanotech Updates on Timing of Clinical In-Field Validation Studies for its COVID-19 Antigen Test

Halifax, Nova Scotia--(Newsfile Corp. - August 6, 2020) - Sona Nanotech Inc. (CSE: SONA), (OTCQB: SNANF) (the "Company"), a developer of rapid, point-of-care diagnostic tests, announces that its previously announced clinical, in-field evaluation studies for its rapid detection, COVID-19 antigen test that commenced in July continue and are now expected to return their full results within two weeks. The delays have been due to ethics review board approvals and a need to make study modifications to accommodate regulatory updates, including for study enrolment criteria and assessment at point of care settings, as well as for test handling procedures.

The evaluation protocol for these studies incorporates aspects of the revised guidance released by the FDA on July 29, 2020. The FDA's new template for commercial developers of non-lab COVID-19 tests included updated guidance on performance evaluation studies, comparator methodology, flex studies, human usability studies, and clinical evaluation, amongst other study components. The Company is committed to the robust evaluation of its COVID-19 antigen test and to submitting a comprehensive data set in its submissions to the FDA and Health Canada that adheres to its recommended guidance. For more information on the new FDA guidance, please see: <a href="https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-posts-new-template-home-and-over-counter-diagnostic-tests-use-non">https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-posts-new-template-home-and-over-counter-diagnostic-tests-use-non</a>

The data from these studies will be used to support the Company's analytical and clinical data as part of the submission it will make to Health Canada and the FDA for emergency use authorization ("EUA") approval for its COVID-19 antigen test.

In addition to its in-field clinical evaluation studies, the Company has also provided prototype tests to several potential customers, under 'research use only' labelling, with whom it has entered into letters of intent for larger purchases of its tests. These smaller studies are part of the Company's commitment to maintaining ongoing evaluations of its test in order to understand its performance in a wide range use case scenarios.

Rapid, point-of-care, antigen tests can make a significant contribution to reducing the spread of COVID-19 by detecting the presence of the virus in individuals, potentially before the onset of symptoms. As previously announced, the Company's rapid detection, COVID-19 antigen test's laboratory validation of performance levels resulted in a test sensitivity of 96%, test specificity of 96% and a Limit of Detection ("LOD") of  $2.1 \times 10^2 \, \text{TCID}^{50}$ . One of the purposes of the in-field evaluation testing is to determine, what, if any, effect environmental or containment factors or human errors in sample collection have on test performance.

The Company cautions that its COVID-19 rapid antigen test is not yet approved by the FDA or other regulatory bodies and will update the market as appropriate.

## **Investor Relations Contact:**

Arlen Hansen 604 684 6730 | 1 866 684 6730 arlen@kincommunications.com

## About Sona Nanotech Inc.

Sona Nanotech is a nanotechnology life sciences firm that has developed multiple proprietary methods for the manufacture of various types of gold nanoparticles. The principal business carried out and

intended to be continued by Sona is the development and application of its proprietary technologies for use in multiplex diagnostic testing platforms that will improve performance over existing tests in the market.

Sona Nanotech's gold nanorod particles are CTAB (cetyltrimethylammonium) free, eliminating the toxicity risks associated with the use of other gold nanorod technologies in medical applications. It is expected that Sona Nanotech's gold nanotechnologies may be adapted for use in applications, as a safe and effective delivery system for multiple medical treatments, pending the approval of various regulatory boards including Health Canada and the FDA.

NEITHER THE CANADIAN SECURITIES EXCHANGE NOR ITS REGULATION SERVICES PROVIDER (AS THAT TERM IS DEFINED IN THE POLICIES OF THE CANADIAN SECURITIES EXCHANGE) ACCEPTS RESPONSIBILITY FOR THE ADEQUACY OR ACCURACY OF THIS RELEASE.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION: This press release includes certain "forward-looking statements" under applicable Canadian securities legislation. Forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable, are subject to known and unknown risks, uncertainties, and other factors which may cause the actual results and future events to differ materially from those expressed or implied by such forward-looking statements. There can be no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements. Sona disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.



To view the source version of this press release, please visit <a href="https://www.newsfilecorp.com/release/61245">https://www.newsfilecorp.com/release/61245</a>