

# Sona Nanotech Receives 'Deprioritization' from FDA; Health Canada Evaluation Continues

Halifax, Nova Scotia--(Newsfile Corp. - October 29, 2020) - Sona Nanotech Inc. (CSE: SONA) (OTCQB: SNANF) (the "Company"), a developer of rapid, point-of-care diagnostic tests, received notice from the FDA that the Company's request for an emergency use authorization ("EUA") for the marketing of its rapid COVID-19 antigen test in the United States "is not a priority" and consequently such authorization will not be issued at this time. The FDA cited current EUA request prioritization criteria as including "the public health need for the product" and did not comment on the performance of the Sona test.

Health Canada continues its evaluation of the Company's application for an Interim Order ("IO") authorization for its test as a 'point-of-care' medical diagnostic device. The Company yesterday received additional questions on its application. Also, Health Canada has submitted the Company's tests to the Public Health Agency of Canada's National Microbiology Laboratory for evaluation, which is ongoing.

Sona has already sold tests to Canadian companies under 'research use only' labelling. These tests are being evaluated as a screening tool for the identification of COVID-19 amongst employees. Potential programs envision having employees that test positive with the Sona rapid test designated 'presumed positive', removed from congested work environments and referred to medical professionals for confirmatory testing. This process would allow employers to remove affected staff from the work place, reduce potential spread and help businesses remain open in pandemic conditions. The Company believes that screening individuals in congested environments, whether they be mining operations, airports or long-term care facilities is the best use case for Sona's rapid test and that this added testing tool can play an important role in Canada's response to Covid-19. These tests were manufactured in the Company's in-house manufacturing facility.

The Company continues its manufacturing scale-up activities, having run multiple pilot production batches with a contract manufacturing organization, and is in advanced discussions with other manufacturers. The Company expects to be in a position to ship commercial tests to customers in November, subject to regulatory approval.

David Regan, Chief Executive Officer of Sona Nanotech commented, "*Large companies, employing thousands of people, are telling us that they cannot source rapid antigen tests which they view as critical to their business continuity and for the safety of their employees. Sona's rapid COVID-19 antigen test is perfectly suited to provide this screening function and thereby help support the normal operation of the economy. The demand for these tests by non-governmental entities is growing stronger as we attempt to return to normal in the face of new waves of the virus. While the FDA has indicated that our test is not a priority for them at this time, Sona also submitted its application to Health Canada and remains committed to working with the regulator to achieve Interim Order approval which could allow Sona's rapid COVID-19 antigen test to contribute to the further opening of the economy and the return to a new normal.*"

The Company has also posted the results of its analytical trial data from MRIGlobal and its in-field, clinical trial results with SaudiVax on its website which provides background data on the test's performance. The Company believes that these studies provide strong support for the use of its test for screening, which it believes is essential to mitigate against the need for business shutdowns from virus outbreaks and subsequent waves of COVID-19.

The Sona lab has recently completed work on a the next evolution of its rapid COVID-19 antigen test which aims to use saliva samples, building on its existing technology, providing for less invasive sample collection. The saliva test would use the existing Sona lateral flow cassette. The Company expects to

announce more details and clinical testing plans for the saliva test in the near future. This test would require a separate submission to regulators for approval to be used as a medical diagnostic device.

Sona Nanotech's rapid COVID-19 antigen test offers results within 15 minutes, using a pregnancy-type lateral flow test that is easy to administer and interpret by non-experts without the need for either laboratory equipment or a device to read its results. Underpinned by Sona Nanotech's proprietary, patent-pending, gold nanorod technology, its test showed 85% agreement to RT-PCR results in patients in an in-field study of 99 patients and 96% sensitivity in laboratory studies.

Health Canada has not yet approved the Sona rapid COVID-19 antigen test and the Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the COVID-19 virus (or SARS-2 Coronavirus) at this time.

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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.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION: This press release includes certain "forward-looking statements" under applicable Canadian securities legislation, including statements regarding Sona's anticipated manufacturing capacity, the anticipated use of Sona's rapid COVID-19 antigen test by employers as a screening tool, and the development of saliva test technology[NTD: Need to identify specific FLS in the final PR]. 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, including the risk that Sona may not be successful in obtaining regulatory approvals necessary for the best use of its products, that potential customers may not adopt its products for screening uses, that Sona's saliva test technology may not prove to deliver the same level of testing accuracy and sensitivity as its nasal swab-based test, that Sona may not be successful in identifying or reaching agreements with additional manufacturing partners, that Sona's manufacturing partners are not able to scale up manufacturing of Sona's products to the anticipated level, that raw materials may not be

available in the amounts or on the schedules required to achieve Sona's manufacturing targets and that regulatory requirements may change. [NTD: Need to identify risks specifically applicable to the identified FLS] 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.



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