Sixth Wave AMIPs(TM) Demonstrate Virus Detection in Saliva Samples

written by Raj Shah | December 14, 2021
December 14, 2021 (Source) - Sixth Wave Innovations Inc. (CSE: SIXW) (OTCQB: SIXWF) (FSE: AHUH) ("Sixth Wave", "SIXW" or the "Company") is pleased to announce it has successfully demonstrated selective binding and detection of live SARS-CoV-2 virus in saliva samples using its patent-pending Accelerated Molecularly Imprinted Polymer ("AMIPs™") technology.

The Company along with researchers at the La Ki Shing Institute of Virology are currently testing with AMIPs™ using saliva samples spiked with live SARS-CoV-2 virus using a protocol similar to an enzyme-linked immunosorbent assay (ELISA) clinical test, a technique well established in the industry. Detection of the virus in saliva samples is a critical deliverable in the development of the AMIPs™ technology. Positive detection results have been achieved at increasingly lower viral loads and are nearing levels indicative of those present in people actively contagious with COVID-19. The results have been independently verified to validate the efficacy of virus binding directly to AMIPs™. An independent parallel assay, using an immunoassay protocol, validated virus binding and indicated that AMIPs™ are approaching the sensitivity needed in clinical assays.

"The rapid progress of the AMIPs™ technology has been remarkable," said Dr. Mike Joyce, a virologist at the La Ki Shing Institute of Virology. "In a very short time, this technology has progressed from something that was very much basic research and non-existent in the diagnostic field to the cusp of real products capable of helping in the fight against

COVID-19. The testing being conducted is following all the steps required for moving the project forward to clinical trials and amassing the needed data for eventual submission to regulatory bodies. This technology has the potential to rapidly expand and address new and existing viral outbreaks. There are many unique traits to the AMIPs™ technology that can't be matched with current technologies and AMIPS™ show promise in addressing several of the unmet needs in the space," he added.

The company's collaboration with Dr. Michael Serpe at the University of Alberta Chemistry Department has completed the initial run of advanced manufacturing techniques implemented into the AMIPs™ prototype and focused on lowering detection thresholds and simplifying the reading of the color changes. The advanced manufacturing techniques use Focused Ion Beam technology to etch a nanometer-scale microarray pattern used for standardizing the virus template during the imprinting process. The microarray is a reusable component used for imprinting and forming the AMIPs™ polymer layer during manufacturing. The reusability of the component promises to enhance performance and simplify production while having a negligible impact on cost.

AMIPs - Next Steps

The next and final stage of laboratory-based development, viral selectivity screening, has commenced. Initial experiments are being run against representative enveloped and non-enveloped viruses. A viral envelope is the outer layer of many viruses and is a key structural determinant of enveloped viruses housing the proteins involved in virus entry into a cell. Among the respiratory viruses, coronaviruses and flu are enveloped while rhinoviruses are not. Testing will be expanded to a standardized panel of respiratory viruses to confirm that there is no cross-reactivity. Completion of the cross-reactivity testing is the last scientific development step required to produce specificity

data before the Company can begin the process of applying for regulatory approval from government agencies such as the FDA and Health Canada.

Of particular note, the advancements in AMIPs™ come at a time that rapid antigen tests are being deployed but not universally accepted by health professionals and regulatory agencies. As highlighted in a Media Release on Dec. 10, 2021, while millions of such tests are being provided by the Government of Ontario, the Grey Bruce Health Unit is NOT recommending use for school students. Lack of accuracy and false reassurance is cited due to repeated and frequent testing not being available and the potentially detrimental effects of false positives on peoples' lives while waiting for follow-up PCR testing.

(https://www.publichealthgreybruce.on.ca/About-Us/News-Releases/ ArticleID/954/COVID-19-Testing-in-Grey-Bruce-Schools-Holiday-Preparations)

The article highlights that after years of the pandemic, antigen tests have failed to deliver adequate accuracy and new technologies are needed, especially in the area of inexpensive over-the-counter diagnostics, to meet the challenges of COVID-19.

The Company is not making any express or implied claims that its current AMIPs™ product has the ability to eliminate, cure, contain, or detect, at a commercial level, COVID-19 (or SARS-2 coronavirus) at this time.

For more information on the AMIPs™ and associated molecular imprinting technology, please visit: https://www.amips.com.

About Sixth Wave

Sixth Wave is a nanotechnology company with patented

technologies that focus on extraction and detection of target substances at the molecular level using highly specialized Molecularly Imprinted Polymers (MIPs). The Company is in the process of a commercial rollout of its Affinity™ cannabinoid purification system, as well as, IXOS®, a line of extraction polymers for the gold mining industry. The Company is in the development stages of a rapid diagnostic test for viruses under the Accelerated MIPs (AMIPs™) label.

Sixth Wave can design, develop and commercialize MIP solutions across a broad spectrum of industries. The company is focused on nanotechnology architectures that are highly relevant for the detection and separation of viruses, biogenic amines, and other pathogens, for which the Company has products at various stages of development.

For more information about Sixth Wave, please visit our website at: www.sixthwave.com

ON BEHALF OF THE BOARD OF DIRECTORS

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Cautionary Notes

This press release includes certain statements that may be deemed "forward-looking statements" including statements regarding the planned use of proceeds and performance of the $AMIPs^{\text{TM}}$ technologies. All statements in this release, other than statements of historical facts, that address future events or developments that the Company expects, are forward-looking statements. Although the Company believes the expectations

expressed in such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance, and actual events or developments may differ materially from those in forward-looking statements. Such forward-looking statements necessarily involve known and unknown risks and uncertainties, which may cause the Company's actual performance and financial results in future periods to differ materially from any projections of future performance or results expressed or implied by such forward-looking statements. In particular, successful development and commercialization of the AMIPs™ technology are subject to the risk that the AMIPs™ technology may not prove to be successful in detecting virus targets effectively or at all, the uncertainty of medical product development, the uncertainty of timing or availability of required regulatory approvals, lack of track record of developing products for medical applications and the need for additional capital to carry out product development activities. The value of any products ultimately developed could be negatively impacted if the patent is not granted. The Company has not yet completed the development of a prototype for the product that is subject of its patent application and has not yet applied for regulatory approval for the use of this product from any regulatory agency.