Sixth Wave Demonstrates Colorimetric Detection of SARS-CoV-2 Utilizing AMIPs(TM)

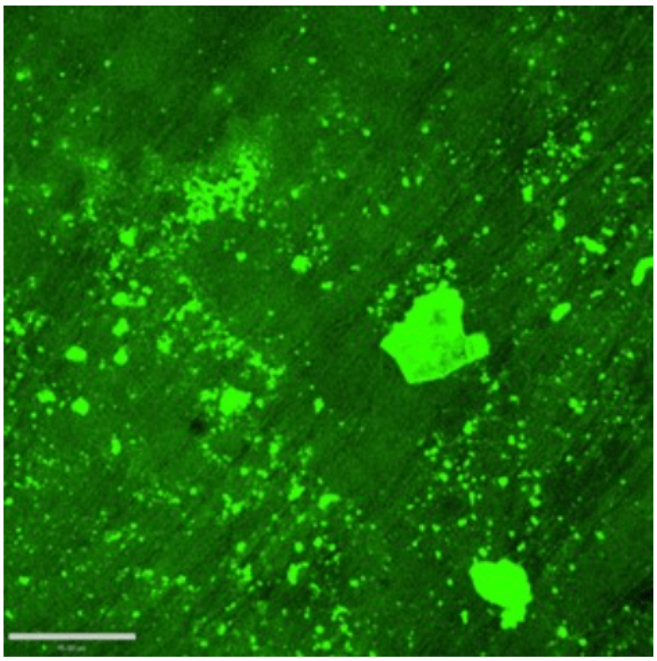
written by Raj Shah | April 14, 2021

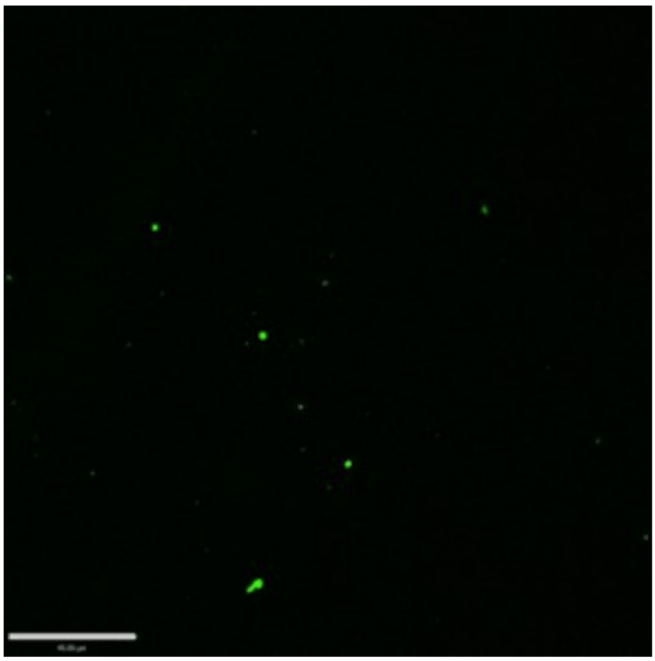
April 14, 2021 (Source) – **Sixth Wave Innovations Inc. (CSE: SIXW) (OTCQB: ATURF) (FSE: AHUH) ("Sixth Wave", "SIXW" or the "Company")** is pleased to announce that it has successfully demonstrated colorimetric detection of SARS-CoV-2, the virus that causes COVID-19 (the "**Virus**") utilizing the Company's patent pending Accelerated Molecular Imprinted Polymers ("**AMIPs™**") technology.

Colorimetric detection is a method of identifying the presence of a target substance within a test sample by means of a color reagent. When successfully applied, the activation of the reagent indicates the presence of the target substance.

The demonstration, performed by way of a simulated synthetic enzyme-linked immunosorbent assay ("**ELISA**") test, is represented by the following microscopic images:

Fig 1: Colorimetric Response of AMIPs™ to SARS-CoV-2 Virus





The image on the left shows the AMIPs™ polymer having been exposed to SARS-CoV-2, with the fluorescent highlights indicating the presence of the Virus. The image on the right shows the AMIPs™ polymer having been exposed to a non-infected sample. (Images produced using Olympus spinning disk Confocal microscope at ONLY 20x magnification).

The Company intends to build on this initial validation toward the development of a colorimetric sensor for a potentially wide range of rapid Virus detection devices using AMIPs™. The spectrum of prospective products includes SIXW's SmartMask™ (see SIXW Press Release dated May 15, 2020), in addition to, airborne sensors, breathalyzers, synthetic ELISA-like tests, cartridge/lateral flow tests, and others.

"*Colorimetric detection is an important development for* AMIPs™ *technology," said Dr. Jon Gluckman, President and CEO of Sixth Wave. "As previously disclosed, the AMIPs™ polymer captures the COVID-19 virus, as intended, and is now supported by three independent analytical methods. Two primary objectives of any rapid diagnostic tool are definitive results and ease of interpretation. Colorimetric Sensors can deliver on both fronts*

and this is a material step in that direction."

"As previously disclosed, AMIPs™ are designed to be resistant to loss in efficacy due to virus mutation and emergence of variants which may change the specific antibody/antigen reaction but have yet to create gross changes to the size and shape of the Virus. AMIPs™ also *has the potential to identify multiple types of viruses (coronavirus, influenza virus, rhinovirus etc.) in a single platform," said Garrett Kraft, Sixth Wave's Lead* AMIPs™ *researcher. "The confirmation of colorimetric detection from this test opens the possibility of deploying a palette of colors to identify multiple viruses in a single pass such as influenza AND COVID-19 with different colors for each. This potential for independent color coding is perhaps the most promising aspect of* AMIPs™ *as a versatile diagnostic tool. Ideally, our end* AMIPs™ *product will be a 'Swiss Army Knife' of sorts, performing multiple diagnostic tests in a single application."*

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

Details on Initial Colorimetric Detection Test Work

The test performed was designed to simulate an ELISA test but using AMIPs™. ELISA tests are a go-to detection technology employed extensively in the health services arena. In its most basic form, ELISA starts by isolating a target pathogen such as SARS-CoV-2 (the "**Antigen**"). The Antigen is immobilized on a solid surface known as a microplate. An antibody targeted for the pathogen (the "**Antibody**"), will have an associated enzyme (the "**Reporter Enzyme**"). When the Antibody binds to the immobilized Antigen the Reporter Enzyme is chemically bound to

the virus. The sample is rinsed to remove unbound Reporter Enzyme, only leaving the Reporter Enzymes that are bound to the virus. An indicator solution is incubated with the sample and any Reporter Enzymes in the sample will catalyze a chemical reaction, thus inducing a color change. From the color change, the researcher can infer that binding between the Antigen and Antibody has occurred, and that the target pathogen (the Virus) is present. The foregoing process produces the colorimetric response that represents detection of a virus.

Using the foregoing ELISA methodology as a starting point, Sixth Wave researchers modified the technique to accommodate the unique features of AMIPs™ molecular imprinting technology. As with all immunoassay tests, ELISA tests require the use of an Antibody-Antigen binding for detection. AMIPs™ replaces the Antibody with a molecular imprint of the whole Virus, and replaces the Antibody with the AMIPs™ imprinted polymer. A chemically engineered binding mechanism built into the polymer, provides a force of attraction between the Virus and the AMIPs™ eliminating any need of biological material including Antibodies. The Reporter Enzymes in classic ELISA tests help amplify the color response making detection easier and, while it was not needed in this test, may be useful in certain AMIPs™ products. The value of AMIPs™ in this regard is multifold:

- **Simplicity & Flexibility** – AMIPs™ test does not require the use of Antibodies, which are biological materials subject to supply chain complexity (must be grown in host animals subsequently sacrificed, stored/transported under refrigeration/freezing), degradation from environmental factors (heat, sun, etc.) which limit how they can be deployed, and as of yet have not been easily configured to detect multiple viruses in a single test. In an ELISA type configuration AMIPs™ can provide the same performance and form factor clinical laboratory workers are accustom to

while providing a robust, reliable, and lower cost product.

- **Robust Detection Capability –** AMIPs™ should be more robust in its ability to detect variants of COVID-19. This is because the mechanism used to capture and immobilize the Virus is not keyed to a specific Antigen-Antibody relationship. The Antigen-Antibody relationship is based on antibody interactions with a small section of a viral protein. This interaction is highly specific but constantly challenged with an ever-changing set of variables due to natural mutation, with significant changes in the Antigen (virus) making it resistant or "invisible" to existing Antibodies.
- **Variants –** As already well documented for many viruses (i.e COVID-19 and influenza) several of the variants of COVID-19 are more transmittable and more deadly (including the United Kingdom, South African, and Brazilian variants) due to such mutation. Immunoassay tests as a class which rely on Antibodies for immobilization and detection of the Virus are ultimately subject to the same inherent potential to miss both known and emergent variants in the same way the human body's immunity can be bypassed and as such may be much more susceptible to false negative results than the more wholistic capture and detection methods implemented in AMIPs™.
- **Additional Validation** – The AMIPs test provides additional validation that the AMIPs™ polymer works. The latter being in addition to the QCM/QCM-D and AFM confirmations previously announced.

The research results obtained directly compared the prototype AMIPs™ polymer against infected and non-infected cell cultures to ensure detection was based on the presence of the virus and not binding of any other components of the cellular milieu or non-specific interactions between the polymer and the

fluorescent dye. Detection was observed using an Olympus spinning disk Confocal microscope. In lay terms, two AMIP™ sensors were used in the experiment. One sensor was exposed to an infected cell culture solution and the other sensor was exposed to a non-infected cell culture solution. Both sensors were then washed to remove unbound material. The AMIPs™ were then exposed to the off-the-shelf florescent dye in accordance with the manufacturer's standard protocols. The dye has chemical functionalities that will react non-specifically with most proteins. The dye solution was then washed off and the sensors were imaged under the microscope at 20x magnification. The results were overwhelmingly clear – AMIPs™ showed detection. No florescent response was observed from the sensor exposed to non-infected cell culture solution. The results demonstrate that the AMIPs polymer selectively binds the SARS-CoV-2 virus and that there are no non-specific interactions between the AMIP polymer and common cellular components or interferants.

Completion of Briefing to Nova Scotia COVID-19 Response Council

The Company is also pleased to report that it has successfully completed its final briefing to the Nova Scotia COVID-19 Response Council. This was well received and represents the final deliverable under the awarded Contribution Agreement previously announced on October 27, 2020 (the "**Council**" and the "**Contribution Agreement** ", respectively).

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 web site at: www.sixthwave.com

ON BEHALF OF THE BOARD OF DIRECTORS

"Jonathan Gluckman"
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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™ 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.