*e*TrueNorth Enabling Patient Recruitment in Clinical Trial to Accelerate the Use of Wearable Diagnostics for Early Identification and Containment of COVID-19

Public Private Partnership includes HHS, DoD, USARMRDC, University of Wisconsin, Philips, BioIntelliSense and eTrueNorth to evaluate if continuous health monitoring can help provide confidence in detecting infection

*Fort Worth, 12-22-2020 –e*TrueNorth the U.S.-based healthcare technology company that enables laboratory testing at retail pharmacies and enables all surge drive-through COVID-19 specimen collection sites, is partnering with the U.S. Department of Health and Human Services (HHS), the University of Wisconsin, Philips and BioIntelliSense Inc. under a US Army Medical Research Development Command (USAMRDC) funded award through the Medical Technology Enterprise Consortium (MTEC) to validate BioIntelliSense's FDA-cleared BioSticker device for the early detection of COVID-19 symptoms. This clinical trial is evaluating the use of wearable diagnostics for early identification and containment of COVID-19 cases.

Philips a global leader in health technology, and BioIntelliSense is a continuous health monitoring and clinical intelligence company. The USARMRDC funded trial hopes to recruit 2,500 volunteers from 22 testing sites located at University of Wisconsin facilities. Participants in the study will be shipped a wearable medical device (BioIntelliSense's BioSticker with its BioHub wireless gateway) that will continuously capture vital signs for 14 consecutive days.

Using *e*TrueNorth's technology platform, individuals can find a nearby location, schedule an appointment, print a voucher and when they arrive onsite, the test results are provided in about 10 minutes. The rapid testing is funded by HHS.

"This is a perfect example of a public-private partnership where all parties are coming together to help Americans fight COVID," said Coral May, *e*TrueNorth's CEO. "We have 22 testing sites where we can immediately identify potential participants for this important study and communicate with them about their potential participation. *e*TrueNorth will work with BioIntelliSense and Philips to validate data. With Americans' participation, private industry and the Federal government are searching for new ways to overcome this pandemic and improve the health of individuals."

To qualify for participation in this study, individuals must have received a COVID-19 test in the past 24 hours for one of the following reasons:

- Recent high-risk exposure to known COVID-19 infected individual(s) within the past 72 hours
- Recent onset of COVID-19 symptoms within the past 72 hours

Individuals may learn more about the study eligibility and enroll online at www.BioStickerCOVIDstudy.com.

To schedule an appointment at one of the 22 COVID-19 rapid testing sites in Wisconsin that will identify participants for this study, individuals should visit www.doineedacovid19test.com.

The BioSticker medical device will be worn by study participants for 14 days and will continuously monitor their:

- Temperature,
- Respiration rate at rest,
- Heart rate at rest,
- Sleep/rest/active state,
- Body position, and/or
- Coughing frequency.

The BioSticker data will automatically transmit via the BioHub wireless gateway to the study database for analysis and validation of the BioSignature COVID-19 symptom detection algorithm.

"As we continue to provide COVID-19 testing resources for Americans, we are also constantly looking for innovative opportunities to bring together healthcare organizations to improve early detection, avoid hospitalizations and quicken recovery of those who test positive for COVID-19," said RADM Erica Schwartz, MD, JD, Deputy U.S. Surgeon General. "This trial is a unique way to bring together such organizations to collect data in an attempt to better understand COVID-19."

The University of Wisconsin Health System president Tommy Thompson expressed the university's willingness to increase access to COVID-19 testing and participate in the clinical study recruitment effort. "By virtue of hosting 22 testing sites at university facilities, we are expanding access to our students, faculty and staff as well as members of the state-wide community to receive a rapid COVID-19 test," said Thompson. "Further, the university is very enthusiastic to help promote a high-technology clinical study that has the potential to help identify COVID-19-positive individuals as quickly as possible. By working collaboratively, we can help overcome this pandemic. The University of Wisconsin is more than pleased to be a part of this effort."

Commander Christopher Steele, Director of the Military Operational Medicine Research Program at USAMRDC, said "Key industry and academic partnerships provide DoD a timely opportunity to field medical-grade wearables capable of high-frequency physiologic surveillance. Our goals are to capitalize on mature, wearable tech and validate predictive algorithms to identify COVID-19 positive individuals that have yet to show clear medical symptoms. Outputs can directly maximize military preparedness and provide immediate benefit for the general population as these tools can be used outside of medical treatment facilities."

James Mault, MD, founder and CEO of BioIntelliSense, explained the importance this study may have on COVID-19 treatment. "The medical-grade BioSticker wearable, combined with advanced diagnostic algorithms, may serve as the basis for identifying pre- and very early symptomatic COVID-19 cases, allow for earlier treatment of infected individuals, and reduce the spread of the virus to others," said Dr. Mault.

About US Army Medical Research and Development Command - The U.S. Army Medical Research and Development Command is the Army's medical materiel developer, with responsibility for medical research, development, and acquisition. USAMRDC produces medical solutions for the battlefield with a focus on various areas of biomedical research, including military infectious diseases, combat casualty care, military operational medicine, medical chemical and biological defense, and clinical and rehabilitative medicine.

About Medical Technology Enterprise Consortium MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transactional Agreement with the U.S. Army Medical Research and Development Command. To find out more about MTEC, visit www.mtec-sc.org.

The views expressed in this news release/article are those of the authors and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

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