Abbott, The U.S. Department Of Defense And TRACK-TBI Partner To Study Point-Of-Care Blood Test For Concussions

-- Academic, military and healthcare leaders have come together to conduct a scientifically rigorous clinical trial of a blood test in development for the brain

-- Research could lead to the first point-of-care blood test of its kind to help evaluate concussions within minutes

ABBOTT PARK, Ill., April 30, 2019 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the next phase of partnership with the U.S. Department of Defense (DoD) and researchers from the **T**ransforming **R**esearch and **C**linical **K**nowledge in **T**raumatic **B**rain **I**njury (TRACK-TBI) Network, one of the largest traumatic brain injury (TBI) efforts of its kind. Together the groups will conduct a clinical trial to evaluate the effectiveness of Abbott's point-of-care blood test technology, which is under development to help clinicians assess brain injuries within minutes, using only a few drops of a patient's blood.[1-2]

"Traumatic brain injury is a significant health issue affecting both active Service Members and Veterans, and we are committed to developing solutions for those impacted by brain injury," said Krista Caudle, Ph.D., project manager, Neurotrauma and Psychological Health Project Management Office, U.S. Army Medical Materiel Development Activity (USAMMDA). "Having a portable biomarker technology will give clinicians an objective measure of a Soldier's brain injury in a matter of minutes and could potentially impact the care they receive when they are evaluated and treated."

A blood test for the brain takes robust, proven data

More than 380,000 military members have sustained TBIs over the past 20 years.[3] To help improve efforts around this complex injury, Abbott and the DoD began their work in 2014 to develop a portable blood test that helps assess concussions right by a person's side. As blood tests are relied on by healthcare providers to detect a variety of conditions due to their objectivity and speed, there's been a growing need to develop a point-of-care blood test that could serve as a warning bell to clinicians that further evaluation is needed.

"Developing a blood test for the brain takes robust, proven data and collaboration among the best minds in academia, industry and the public service sectors," said Beth McQuiston, M.D., R.D., board-certified neurologist and medical director, Diagnostics, Abbott. "This type of blood test could give clinicians more real-time, objective information about what's happening to the brain, so they can make timely, accurate decisions right at the point of care."

As the global leader in diagnostic point-of-care testing, Abbott has more than 120 scientists who are researching and developing Abbott's concussion assessment test for the next generation i-STAT® Alinity® system.[1-2] The i-STAT system, which is already in use within the military as well as in hospitals globally, performs a number of common blood tests within minutes – at the bedside – and uses only two to three drops of blood.

The power of partnerships to address brain health

The blood test under development by Abbott would measure two types of proteins – GFAP and UCH-L1 – that are released from the brain and into the blood when the brain is injured.[4] Blood biomarkers, such as GFAP and UCH-L1, have been researched for more than a decade for their ability to help assess traumatic brain injury in both the military and the general public.

A critical part of the TRACK-TBI research initiative is to evaluate the effectiveness of blood-based biomarkers to detect brain injury. Abbott and the DoD will work with researchers from TRACK-TBI for this clinical trial to analyze data collected from patients who come to top trauma centers across the country. Currently, the U.S. Food and Drug Administration (FDA) has cleared a blood test that detects brain injury within 12 hours of injury. As part of this clinical trial, researchers will evaluate people with suspected TBI within 24 hours of injury and compare their blood test results against traditional clinical assessments, computerized tomography (CT) scans, magnetic resonance imaging (MRI) scans and clinical outcomes.

"Whether on the battlefield or in the emergency room, we need quick and accurate information to help assess a person who may have sustained brain injury," said Geoffrey T. Manley, M.D., Ph.D., principal investigator of TRACK-TBI, neurosurgeon and professor of neurosurgery, University of California, San Francisco (UCSF). "Our goal with this partnership is to validate the scientific rigor behind new technologies, like this blood test, and how they can help ensure the best care for our troops and patients."

About TRACK-TBI:

The **T**ransforming **R**esearch and **C**linical **K**nowledge in **T**raumatic **B**rain **I**njury **Net**work (**TRACK-TBI NET**) is a collaborative research effort funded by the National Institute of Neurological Disorders and Stroke (NINDS), the U.S. Department of Defense (DoD) through U.S. Army Medical Research and Materiel Command (USAMRMC) and U.S. Army Medical Materiel Development Activity (USAMMDA), with support from private and philanthropic partners. TRACK-TBI evolved from the largest and most comprehensive precision natural history study of TBI ever conducted in the U.S. The foundational observational study enrolled more than 3,000 TBI patients across the age (0-100 years old) and injury spectrums from concussion to coma, along with separate orthopedic (n=300) and friend control cohorts (n=300), at 18 U.S. Level 1 trauma center study sites.

About Abbott:

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 103,000 colleagues serve people in more than 160 countries.

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1. Abbott's concussion assessment test is currently in development and is for research purposes only. It is not yet commercially available.
2. Abbott's i-STAT Alinity is available outside of the U.S. and is not yet commercially available in the U.S.
3. Defense and Veterans Brain Injury Center. DoD Worldwide Numbers for TBI. AccessedMarch 7, 2019. https://dvbic.dcoe.mil/dod-worldwide-numbers-tbi
4. GFAP stands for the glial fibrillary acidic protein and UCH-L1 stands for the ubiquitin carboxyl-terminal hydrolase L1.

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In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).

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