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FOR IMMEDIATE RELEASE

ALS Biomarkers Review Calls for Consortium to Speed Progress

Washington, D.C. (January 5, 2016) — Biomarkers to track disease progression are central to the search for new therapies in ALS. A new review of biomarker development in ALS, authored by top experts in the field and supported by The ALS Association, provides an overview of the state of biomarker development and calls for the formation of an ALS Biomarker Consortium to coordinate efforts among all stakeholders. The ALS Association is taking the lead to initiate this effort. The collaboration of this publication's authors is also vital in advising the formation of the FDA Guidance Document for ALS clinical trials.

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Eventually, people with ALS lose the ability to initiate and control muscle movement, which often leads to total paralysis and death within two to five years of diagnosis. For unknown reasons, veterans are twice as likely to develop ALS as the general population. There is no cure, and only one drug approved by the U.S. Food and Drug Administration (FDA) modestly extends survival.

The review, titled "ALS Biomarkers for Therapy Development: State of the Field & Future Directions," is by Michael Benatar M.D., Ph.D., of the University of Miami, Kevin Boylan M.D., of the Mayo Clinic in Jacksonville, Florida, Andreas Jeromin Ph.D., of Iron Horse Diagnostics in Phoenix, Seward B. Rutkove M.D., of Beth Israel Deaconess Medical Center in Boston, James Berry M.D. and Nazem Atassi M.D., both of Massachusetts General Hospital in Boston, and Lucie Bruijn, Ph.D., M.B.A., Chief Scientist for the ALS Association. The review was recently published in the journal [Muscle & Nerve](#).

The need for validated biomarkers for ALS has taken on increased significance with the ongoing development of a Guidance Document from the Food and Drug Administration for ALS clinical trials that was recently spearheaded by The ALS Association. The named authors are currently working together and are key in advising the biomarker topic area that will be incorporated into the Guidance Document. The document is intended to increase the ability of drug companies to move quickly to clinical tests of new therapies. The availability of validated biomarkers is likely to further speed that ability, allowing new drugs to be tested in the fastest possible timeframe.

The review and the recognition of a pressing need for an ALS Biomarker Consortium grew out of a series of meetings, including the following: a biomarker workshop co-sponsored by the ALS Association and ALS Therapy Development Institute (TDI) in May 2014; a biomarker symposium at the first annual ALS Research Group meeting in September 2014; and, the emergence of the Clinical Research in ALS and related disorders for Therapeutic Development (CRaTe) Consortium, a National Institutes of Health (NIH)-supported effort for which the discovery and validation of biomarkers relevant to therapy development is a specific focus.

According to the authors of the review, “This is an opportune time for the establishment an ALS Biomarker Consortium (ABC) that includes all relevant stakeholders. If it is to succeed, the structure and governance of this consortium must recognize and accommodate the complexity of the ALS research landscape, including the number and diversity of stakeholders who may often have competing interests,” like academic researchers, small biotech companies, and large pharmaceutical companies. “All parties must (and indeed do) recognize that all efforts are ultimately directed towards, and expended in, serving the needs of our ALS patient population...[W]e propose a federated model, in which all interested and willing stakeholders may participate with equal opportunity to contribute to the broader mission of biomarker development and validation.”

“The ALS Association has invested significant funds towards the development of biomarkers for ALS and will continue its commitment by investing further funds to establish an ALS Biomarker Consortium and seeks dedicated involvement from all stakeholders,” Dr. Bruijn emphasized. An initial call for participants will be forthcoming.

About The ALS Association

The ALS Association is the only national non-profit organization fighting Lou Gehrig’s Disease on every front. By leading the way in global research, providing assistance for people with ALS through a nationwide network of chapters, coordinating multidisciplinary care through certified clinical care centers, and fostering government partnerships, The Association builds hope and enhances quality of life while aggressively searching for new treatments and a cure. For more information about The ALS Association, visit our website at www.alsa.org.