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European Medicines Agency Deems Imaging Biomarker a Qualified Measure to Select Patients with Early Stages of Cognitive Impairment for Alzheimer's Disease Clinical Trials

Tucson, Arizona, January 23, 2012 – Based on a request for regulatory review by Critical Path Institute's (C-Path) Coalition Against Major Diseases (CAMD), the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use has issued a positive opinion on the use of magnetic resonance imaging (MRI) to measure hippocampal volume as a tool to enrich recruitment into regulated clinical trials in the pre-dementia stage of Alzheimer's disease (AD). This is the first imaging-based biomarker for AD to be granted a positive opinion by a regulatory agency.

With the explosion of the at-risk population and the skyrocketing cost of care, there is an acute need for effective medicines that can slow or halt the progression of AD. There is growing consensus in the Alzheimer's field that therapeutic intervention at an early, mildly symptomatic stage – or even before the emergence of memory and thinking deficits – may be required to preserve essential cognition and function.

"While incremental progress is being made in understanding Alzheimer's disease, attempts to identify pre-symptomatic patients have met with limited success. This has meant that therapeutic trials have had to focus on the later stages of Alzheimer's, where observing drug improvement is less likely," said Raymond Woosley, MD, PhD, President and CEO of C-Path. "Hippocampal volume is the most widely studied quantitative MRI measure used to assess progression in AD patients, and one of the few biomarkers studied to date that correlates with cognitive impairment."

The hippocampus is the part of the brain that is involved in forming, organizing, and storing memories.

It is anticipated that selecting patients for an Alzheimer's clinical trial on the basis of low hippocampal volume will give researchers increased confidence that the study participants will progress to true Alzheimer's dementia. Such methodologies will help ensure that patients with cognitive impairment due to other causes will be properly excluded from tests of new Alzheimer's therapies, and thereby not expose them to drug candidates that will not likely help their condition.

"The qualification of biological markers such as hippocampal volume for Alzheimer's clinical trials is critical to the advancement of the field and the acceleration of developing new therapies and diagnostic tools," said Maria Carrillo, PhD, Senior Director of Medical and Scientific Relations at the Alzheimer's Association. "Published research has indicated that several biomarkers are good possibilities and these need to be investigated further with a focus on global standardization, as rapidly as possible."

Knowing where regulatory agencies stand on certain methods or techniques like hippocampal volume helps researchers design clinical trials that are more likely to meet regulatory requirements. Input from regulatory agencies on biomarkers is also beneficial to pharmaceutical companies, as they can share the expense of evaluating and advancing these drug development tools with their peers.

"These regulatory qualifications are not about how we make a diagnosis of Alzheimer's in the doctor's office. What we want to do is improve the selection of patients for research, and in that way improve the likelihood of success of clinical trials that test new Alzheimer's treatments," said Maria Isaac, MASc, MD, PhD, Scientific Administrator, Science Advice & Orphan Drugs Sector, EMA. "We think that combining clinical diagnosis with biomarkers will help us better choose a clinical study population that will give us the best data," said Dr. Isaac.

The EMA, headquartered in London, U.K., is responsible for regulatory approval of medicines in the European Union (EU). Its qualification opinions provide guidance on new methodologies. It includes qualification of biomarkers developed by consortia, networks, public/private partnerships, or the pharmaceutical industry for a specific intended use in pharmaceutical research and development.

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ABOUT CRITICAL PATH INSTITUTE (C-PATH): An independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona (SFAz), and the U.S. Food and Drug Administration (FDA), C-Path is committed to improving health and saving lives by accelerating the development of safe, effective medicines. An international leader in forming collaborations around this mission, C-Path has established global, public-private partnerships that currently include over 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and thirty five major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona, with an office in Rockville, Maryland. For more information, visit www.c-path.org and follow us on Facebook. Click here to view a video showing why the work of C-Path is essential.

The C-Path Vision: Creating collaborations that advance scientific innovations to improve human health and save lives by accelerating the development of safe, effective medicines.

ABOUT THE COALITION AGAINST MAJOR DISEASES (CAMD): The mission of CAMD is to accelerate the development of therapies for neurodegenerative diseases by advancing drug development tools for regulatory approval. CAMD works to identify patients with neurodegenerative diseases before symptoms are apparent, and develop tools to prevent or slow these diseases so patients can maintain independence and quality of life. CAMD is comprised of members from the pharmaceutical industry, global regulatory agencies, patient advocacy groups, research foundations, academia, scientific associations, and consultant groups with a commitment to combating neurodegenerative diseases.