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FDA offers guidance on Alzheimer's drug development

February 8, 2013 | News | By BioSpectrum Bureau



Singapore: The US Food and Drug Administration has issued a proposal designed to assist companies developing new treatments for patients in the early stages of Alzheimer's disease, before the onset of noticeable (overt) dementia.

Alzheimer's disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks of daily living. In most people with Alzheimer's, symptoms first appear after age 60. Alzheimer's disease is the most common cause of dementia among older people.

"The scientific community and the FDA believe that it is critical to identify and study patients with very early Alzheimer's disease before there is too much irreversible injury to the brain," said Dr Russell Katz, director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "It is in this population that most researchers believe that new drugs have the best chance of providing meaningful benefit to patients."

The draft guidance titled, 'Guidance for Industry, Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease', explains the FDA's current thinking about the way researchers can identify and select patients with early Alzheimer's disease, or those who are at risk of developing the disease, for participation in clinical trials. In recent years, the research community has tried to find ways to identify these patients using criteria that are based on biological indicators (biomarkers). Researchers have also tried to develop sensitive clinical measures that can detect subtle mental decline.

"This draft guidance is intended to serve as a focus for continued discussions between the FDA and pharmaceutical sponsors, the academic community, advocacy groups, and the public," adds Dr Katz. "The FDA is committed to vigorously addressing Alzheimer's disease and will work with industry to help develop new treatments in this early population as expeditiously as possible."

For drugs designed to treat patients with overt dementia, the FDA currently requires that treatments not only show an effect on abnormal thinking, but also how well patients function. The goal for these trials is to ensure that any beneficial effect on thinking is associated with a clinically meaningful outcome for the patient, e.g., improvement or lack of decline in how patients feel or function.

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However, because patients with early Alzheimer's disease have little-to-no impairment of global functioning, it is difficult to assess changes in function in these patients. This can make it difficult to determine if a given treatment's effect is clinically important.

FDA is seeking public comment on the draft guidance for 60 days. Instructions on how to submit comments are included in a related Federal Register notice. In finalizing the guidance document, the agency will consider the information received from the public.

The FDA proposal is part of US Department of Health and Human Services' efforts under the National Plan to Address Alzheimer's Disease, which calls for both the government and the private sector to intensify efforts to treat or prevent Alzheimer's and related dementias and to improve care and services. It responds to recommendations from a May 2012 HHS and National Institutes of Health Alzheimer's research summit to conduct clinical trials in at-risk individuals without symptoms and to develop and validate new measures so that Alzheimer's can be measured at the earliest possible time in the course of the disease.