

## **International Regulatory Agencies meet in Rome to tackle together dementia emergency**

*Hosted by AIFA the Second International Regulatory Meeting within the Dementia Integrated Development Initiative, a project led by the United Kingdom*

The second international regulatory meeting focusing on research and development of new treatments for dementia will take place at the Italian Medicines Agencies headquarters on 9<sup>th</sup> and 10<sup>th</sup> June.

The event is sponsored by the Department of Health of the British Government under the "Dementia Integrated Development Initiative".

Representatives from national competent authorities for drugs in the UK, Japan, Canada, United States, Denmark, Germany, Switzerland and from the European Medicines Agency, together with academics, will meet in Rome for a closed-door discussion of high scientific and strategic value. The meeting aims to address the critical issues related to the testing of new treatments for dementia.

The term dementia refers to a group of diseases and clinical conditions characterized by memory and other cognitive functions impairment that generates a progressive reduction of the capability to accomplish daily activities. Among these, the most common is Alzheimer's dementia.

Alzheimer International Association's estimates indicate that in 2013 there were more than 44 million patients with dementia all over the world. This number is expected to rise up to 75 million in 2030 and to exceed 135 million in 2050, with very high overall costs amounting to hundreds of billions of dollars.

Dementias are caused by a degeneration of brain neurons due to different pathophysiological mechanisms. Findings in neuroscience confirmed that the pathological processes that lead to neuronal death over the years begin 15-20 years before the onset of clinical symptoms. This opens up the possibility, though not yet confirmed, to diagnose the disease in its early stages through the use of biomarkers. This would allow an early therapeutic intervention and perhaps contribute to slow the neurodegenerative process that leads to the loss of higher cognitive functions.

However, this perspective requires a collective effort to collect and quickly share epidemiological, clinical and neurobiological data in order to validate the biomarkers, the new diagnostic criteria and the outcome measures. The commitment of all the stakeholders involved should focus on the outline of new models of clinical trials development to confirm the potential of these new therapies to modify the neurodegenerative process, so far considered irreversible.

The cost of research and development cycles of new molecules in neurology, and in particular in the field of dementia, is on average higher than in other therapeutic areas. This is mainly due to the duration of the cycles and to the complexity of disease models in respect, for instance, to infectious diseases, the outcome measures of which are certain and relatively short.

Reducing uncertainty with respect to diagnosis, disease progression and exploiting the opportunity to evaluate the outcome of treatments with reasonable statistical confidence can have a direct impact on the costs of research and may act as an incentive to continue to invest in this field.

*"This is the reason why this meeting that AIFA will have the honor to host is of exceptional importance - declared the Director General of AIFA, Luca Pani. Thanks to the open discussion among major international experts and regulators we expect that new sustainable approaches will emerge, in order to cope with what is otherwise destined to become "The" disease of the coming decades, also because of the progressive aging*

*population. Identifying areas of research and innovative methodologies that can effectively provide hope for the development of a cure for dementia and not just help relieve its symptoms is a challenge that we as scientists and regulators want to responsibly take charge of”.*

*“Italy is the second country in the world with the highest number of people aged over 60 and dementias will soon become a health emergency - adds Valentina Mantua, psychiatrist and senior medical officer at AIFA’s European Assessment Office, and Italian representative in the meeting experts panel. “AIFA’s representatives at the European Scientific Committees have a very strong commitment in this field and are sensitive to the problems of patients and their families, whose lives are heavily affected by these terrible diseases. The pharmaceutical industry has been investing for years in research and development of innovative therapies directly targeted to the molecular mechanisms of the disease, but no treatment is yet available on the market. Regulatory agencies have thus a twofold mandate: on one hand they must ensure that therapies that will prove effective and safe will be available to patients as rapidly as possible, on the other hand they need to ensure sufficient evidence to enable the correct assessment of the benefit/risk ratio of new treatments and understand the real added value of new technologies in terms of health”.*

*“The topic of dementia means a lot to me - concluded Sergio Pecorelli, AIFA Chairman and representative of the Italian government in Brussels in the Steering Committee of the European Innovation Partnership on Active and Healthy Ageing - ”since it is strongly linked to the promotion of an active and healthy aging. I warmly welcome this meeting as a milestone in the support of the elderly population, one of the most fragile in the care process and which requires as targeted and anticipated interventions as possible. In recent decades the prevalence of mental illness, such as different forms of dementia, has dramatically increased in older people, not only due to aging itself, but also because of new emotional and socio-demographic circumstances which the elderly are exposed to. Such a scenario requires a special attention from the medical and regulatory science which must focus on to aspects such as etiology, early diagnosis and innovative treatments for these diseases, supported by a concrete global commitment aiming at the promotion of good prevention practices and correct lifestyles”.*