The ICOD project has received the funding from the European Union's Horizon research and innovation programme under grant agreement n° 899986

Official announcement for the World Down Syndrome Day (21st of March 2021)

The ICOD project is ready to start: the first EU-funded project on an innovative pharmacological approach, Aelis Farma AEF0217 for the treatment of cognitive deficits in Down Syndrome

Down syndrome (DS) is the most common chromosomal abnormality in children leading to lifelong intellectual disability. Over one million people in the EU and US have DS, and its prevalence has increased in the last ten years. Thanks to significant advances in medical and social care, the life expectancy of individuals with DS has increased greatly, so that many of them reach even the age of 60-70.

DS causes lifelong cognitive dysfunction, which results in important negative consequences for these individuals, their families and society. Despite the heavier social burden and the greater medical needs linked to this intellectual disability, there isn't an approved therapy for DS-related cognitive dysfunction yet. Furthermore, though there are specific cognitive screening tests designed for individuals with DS, no official guidelines have been developed to assess their cognitive deficits or their impact on quality of life of DS individuals and their families. Further challenges to be met include the difficulty in dissecting age-related cognitive decline from the underlying intellectual disability, and the lack of international consensus on validated and accepted cognitive psychometric tools able to detect the potential clinical efficacy of a new drug both at preclinical and clinical levels.

The ICOD project (Improving COgnition in Down syndrome) aims to address this unmet clinical need by accelerating the clinical development of AEF0217. This first-in-class new drug belongs to a new pharmacological class the "signaling specific inhibitors of the CB1 receptor (CB1-SSi)" developed by the biotech Aelis Farma. AEF0217 targets the CB1 receptor, whose hyperactivity has been recently linked to cognitive deficits in DS, and is able to reverse cognitive impairments in mouse models of DS that have been evaluated using an innovative translational medicine approach.

The ICOD project will provide a clinical proof of concept for the efficacy of AEF0217 to counter cognitive deficits in DS by performing first in humans (Phase I), as well as proof-of-principle clinical efficacy studies (Phase II) with AEF0217. Aelis Farma will be the sponsor of these studies. The clinical efficacy of AEF0217 will be evaluated through an innovative psychometric approach where the same cognitive psychometric tools adopted at preclinical level will be used also in Phase I/II trials.

The European Consortium of the H2020 EU-funded ICOD project is led by IMIM (Rafael de la Torre, Barcelona, Spain) and AELIS FARMA (Pier Vincenzo Piazza, Bordeaux, France) in collaboration with Oasi Research Institute (Filippo Caraci, UniCT, Catania & Oasi Troina, Italy), Institut Jérôme Lejeune (Sophie Durand, Paris, France), Centre Hospitalier Universitaire (Renaud Touraine, Saint-Etienne, France) and the Hospital Universitario de la Princesa (Diego Real de Asúa, SERMAS, Madrid, Spain).

The final goal of the ICOD project is to make available this innovative first-in-class drug for DS individuals 7 years after its clinical development, offering people with DS and their families a novel approach for the treatment of DS-related cognitive dysfunction.