DeepTrace Technologies Announces CE Mark and European Launch of TRACE4AD: the medical device for the early diagnosis and prognosis of Alzheimer' s disease

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Milan, Italy. DeepTrace Technologies, the Italian spin off of the University School for Advanced Studies IUSS Pavia, announces that TRACE4AD has been granted CE Marking as a medical device. TRACE4AD is a vertical AI-powered tool able to select a subject with mild cognitive impairment that will progress to Alzheimer's disease by a simple automatic reading of the subject MRI brain scan and cognitive measures.

The news arrives a few hours after the FDA approval of Aduhelm, the Biogen's drug against Alzheimer's syndrome that has shown a reduction in brain plaques in patients with the first symptoms of the disease.

"We have achieved the most important milestone of our project and we are pleased to start offering the CE Mark TRACE4AD tool to the European market" said Prof. Isabella Castiglioni, Honorary President of DeepTrace Technologies. "All the more reason now, when hope for a cure opens up, it becomes necessary to be able to identify earlier patients who are affected by the disease, so that they can benefit the most from the therapy".

"Being able to screen mild subjects who would progress to dementia within two years, our tool can be also very useful for monitoring the effects of the drug in those subjects that allow results in a short time, a great advantage for clinical trials and post market monitoring of the drug", commented Christian Salvatore, CEO of DeepTrace. "Thanks to the resources received from the Progress Tech Transfer investment fund, we are working to allow the tool to be widely distributed in Italian and European hospitals, through direct sales channels and authorized resellers. From a technological point of view, the tool is already available all over the world being accessible both locally and on cloud".

"At Centro Diagnostico Italiano we were among the first to believe in the support of artificial intelligence for our work to improve the diagnosis, prognosis and therapy of our patients. In the field of research, we have contributed with DeepTrace Technologies to develop dedicated tools for Radiologists, said Dr Sergio Papa, MD Imaging and Nuclear Medicine Director of Centro Diagnostico Italiano.

About TRACE4AD

TRACE4AD is indicated for subjects at risk of Alzheimer's disease dementia on the recommendation of neurology specialists. Radiology specialists with neuroradiological expertise can use TRACE4D to support the reporting of brain MRI investigations in these subjects. Neurology specialists can use TRACE4AD as an aid to diagnosis and prognosis. TRACE4AD software provides the subject level of risk (low risk or high risk) of being affected by or progressing to Alzheimer's disease dementia within 24 months of the date of the TRACE4AD-processed examination, i.e., the subject's brain MRI investigation, possibly in combination with a neuropsychological examination performed no earlier than and no later than one month from the brain MRI. TRACE4AD may be provided in both on premise (PR), and on cloud (CL) configurations. TRACE4AD showed a sensitivity >85%, specificity > 80%, PPV > 82%, NPV > 85% but its performance improves with time with the training of the tool. It should be noted that DeepTrace Technologies S.R.L. considers TRACE4AD as a support to the neurologists in their diagnosis and prognosis, and as a support to the radiology specialists with neuroradiological expertise in their reporting of brain MRI investigations, who have the sole decision-making responsibility.

About DeepTrace Technologies

DeepTrace Technologies S.r.l. (www.deeptracetech.com) delivers intelligent technologies that augment human capabilities to early detect and predict effects of severe changes in global assets impacting on society. Healthcare is the main one. Based on AI-data driven analyses, DeepTrace technologies provide solutions at low costs and time-savings. These technologies are non-invasive, scalable, replicable, sustainable, and support users' engagement in the decision management providing understandable outputs. Software-as-medical-devices are delivered to the healthcare providers with highly competitive time-to-market.

About Alzheimer's Disease

Worldwide, around 50 million people have dementia, there are nearly 10 million new cases every year and the incidence is set to double in 2050. Alzheimer's disease is the most common form of dementia and may contribute to 60–70% of cases. Between 2000 and 2019, deaths with Alzheimer's disease increased by 145%. For medical specialists, diagnosing Alzheimer's disease at a very early stage is very complex and often inconclusive. It is impossible to predict the prognosis.

About Progress Tech Transfer and MITO Technology

The Progress Tech Transfer fund was launched in January 2019, with a total endowment of 42 million euros and a collection target of 50 million, jointly subscribed by the European Investment Fund (Fei) and by Cassa Depositi e Prestiti (Cdp) in the scope of the ITAtech platform, ENPAIA and other private lenders.

MITO Technology is the Italian company that for ten years has been dealing with the enhancement of research results in support of universities and public bodies and is the strategic advisor of the Progress Tech Transfer fund ensuring the connection with the world of research in Italy for the scouting of technologies and start-ups.

About ITATech

ITAtech is the tool dedicated to the financing of technological transfer processes supported by InnovFin Equity, with the financial backing of the European Union under Horizon 2020 Financial Instruments and the European Fund for Strategic Investments (EFSI) set up under the Investment Plan for Europe. The purpose of EFSI is to help support financing and implementing productive investments in the European Union and to ensure increased access to financing.

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