Pre Diagnostics raises EUR 1.5 million to CE mark early Alzheimer's blood test

Oslo, November 11 2015: Norwegian LGfEGNT2LhmIVD specialist Pre Diagnostics today announced it has completed a EUR 1.5 million funding including a fully subscribed private placement. The moneys will be used to finance CE-marking by early 2017 of the company's lead immunoassay PreDx Ad for early detection of MCI and Alzheimer's. EUR 1 million has been provided in contribution and grants by Innovation Norway and industry partners Fürst Medical Laboratory and Akershus University Hospital AHUS) in Norway. The company also announced that a new grant application is underway, with a third equity issue planned in 2016, to raise a further EUR 1.5 million to fund intervention trials with medical nutrition.

PreDx Ad is a blood-based assay for beta-Amyloid protein degradation products developed from leading research by Professor Tormod Fladby of AHUS. In Alzheimer's disease, beta-Amyloid accumulates in the diseased brain and destroys the nerve cells, a process that eventually leads to dementia. Professor Fladby has shown there is reduced clearance of this protein in the cells responsible for removing beta-Amyloid, namely the macrophages. These can be collected by a blood sample and by showing reduced degradation products of beta-Amyloid early in the disease development in turn open the possibility of earlier intervention. Already a prototype blood assay has indicated that the assay has the potential to perform with similar accuracy to current spinal fluid tests.

"With the new funding, we now aim to develop the prototype fully into a commercial product. The clinical accuracy of the new blood based diagnostic test will be documented in accordance with the European IVD regulations by an ongoing multinational clinical study,"
says CEO Håkon Sæterøy. Akershus University Hospital will lead the study and include samples from 300 Alzheimer cases and controls, focusing primarily on the early predementia disease stages such as MCI. All included patients will undergo full clinical evaluation for dementia, including spinal fluid tests and advanced imaging procedures, in addition to blood sampling and testing with the

new method.

"It is now widely accepted that a new blood-based test with high accuracy in the early disease stages is essential to accelerate effective drug development and intervention within the Alzheimer's space. Pre Diagnostics aims to develop stable blood-based tests that effectively demonstrate any intervention effect on the key disease mechanisms. Thus we are looking to provide a patient recruitment and companion diagnostics tool, not only for drug therapies, but also accessible intervention products, such as high-dose Omega-3."
continues CEO Håkon Sæterøy.