

## **InfanDx receives BMBF grant to develop companion diagnostic test to identify newborns likely to benefit from neuroprotective hypothermia treatment**

**Cologne/Germany, 03 March 2020.** InfanDx AG, a diagnostics company specialized in the development of biomarker-based tests, today announced that it has been awarded a research grant from Germany's Federal Ministry of Education and Research (BMBF) for a joint project with researchers at the University Hospital Essen, Clinic for Pediatrics I, and Furtwangen University. InfanDx will take the lead in the project with a total volume of over EUR 1 million, which will be used to develop a companion diagnostic based on metabolomic biomarkers. While the HypoxE<sup>®</sup> test, currently in late-stage development at InfanDx, aims at identifying whether a newborn is affected by neonatal encephalopathy, this new test format shall serve to predict if an identified newborn is likely to benefit from neuroprotective hypothermia treatment. This makes the new test format an ideal complement to InfanDx' product pipeline.

Infants who have experienced an oxygen deficit during delivery (asphyxia neonatorum) can develop neonatal encephalopathy, which may result in lasting brain damage and life-long disability. An effective therapy using hypothermia exists and can limit or even prevent permanent brain damage. However, only about 50 percent of infants affected by neonatal encephalopathy clearly benefit from this burdening therapy. By developing a diagnostic test based on metabolomic biomarkers, which can differentiate infants who will likely respond to hypothermia treatment from those who likely will not, non-responders will be spared an ineffective therapy and can receive appropriate alternative treatment in the future in order to achieve maximum neuroprotection.

Ron Meyer, CEO of InfanDx, said: "We are honored to receive this grant, which is an important recognition of our current and future development programs aimed at helping newborns avoid life-long disability. This funding will allow us to broaden our test portfolio with a companion diagnostic for neuroprotective hypothermia treatment. The new companion diagnostic, together with the HypoxE<sup>®</sup> test, which aims to reliably identify babies affected by neonatal encephalopathy within the 6-hour timeframe for treatment initiation, will enable neonatologists to make better informed treatment decisions. We are excited to join forces with the Clinic for Pediatrics I at the University Hospital Essen, one of Europe's top Pediatric Departments specialized in neonatal neurology research, and our well-proven partner for metabolomics research at Furtwangen University."

The researchers at the University Hospital Essen will focus on preclinical development and thus prequalify the underlying hypothesis. Furtwangen University will contribute expertise in metabolomic biomarker identification and validation. InfanDx will be able to use pre-existing specimen from clinical research to enable validation of metabolomics results directly in human samples, and will perform clinical follow-up examinations with previous study participants to evaluate their effective health status after hypothermia treatment.

Prof. Dr. rer. nat. habil. Hans-Peter Deigner, dean of the Faculty of Medical and Life Sciences, Hochschule Furtwangen University, and co-founder of InfanDx, commented: "Using metabolomics is an innovative approach to detect brain damage and manage treatment decisions. This also emphasizes the wide applicability of metabolomics in modern diagnostics. I am pleased that the BMBF has recognized the importance of developing new diagnostic tools for infants who may have experienced perinatal asphyxia. Our dedicated skilled research team is driving our work to identify new metabolomic biomarkers with a high predictive value so newborns can receive the best possible care."

Prof. Dr. med. Ursula Felderhoff-Mueser, director of the Clinic for Pediatrics I at the University Hospital Essen, added: "In the clinic, we are often faced with making difficult treatment decisions for newborns who may have experienced perinatal asphyxia. Even if an infant receives a diagnosis of a likely neonatal encephalopathy, there is currently no way for us to know if the standard-of-care treatment, hypothermia, will be effective for this particular patient. By developing an easy-to-use point-of-care diagnostic tool that

can differentiate responders from non-responders, we are optimistic that, together, we can close an important gap in the clinical care of infants.”

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**About InfanDx**

InfanDx AG is a privately held company established in 2010 in Cologne, Germany. The company focuses on the development of a new generation of diagnostic tests based on biomarkers derived from an integrated combination of genomics, proteomics and particularly metabolomics research. Lead product candidate is the InfanDx HypoxE-test® for rapid and reliable diagnosis of perinatal asphyxia (oxygen deficit during birth), a major cause for brain injury often followed by life-long disability. Treatment is available only if initiated within six hours from birth. As first in class, the InfanDx HypoxE-test® will be able to deliver reliable results within this time frame. The test itself and its accompanying diagnostic instrument are currently in clinical development. Other biomarker-based diagnostics are in development. For more information, please visit: <http://www.infandx.de/>

**About the Clinic for Pediatrics I/Center for children and youth medicine, University Hospital Essen**

The Clinic for Pediatrics I, Neonatology, Ped. Intensive Care and Pediatric Neurology, of the University Hospital Essen has a long-standing expertise in translational experimental research on mechanisms of neonatal brain injury. The research unit in close proximity to the clinic runs a variety of experimental set-ups such as perinatal asphyxia, inflammation and hyperoxia to model developmental brain injury in term-born and preterm infants. The overall aim is to identify biomarkers indicating injury, and target mechanisms for future neuroprotection. Furthermore, clinical research in Neonatology focuses on identification of blood and also technical biomarkers in combination with long-term follow-up studies in order to better predict brain injury (i.e. aEEG, MRI at term equivalent age, executive functions, cerebellar function).

**About Furtwangen University**

Furtwangen University (HFU) is one of Germany's leading universities of applied sciences, whose core business is science-based, practice-oriented education and training. Traditional boundaries between subject fields are removed in interdisciplinary projects. HFU is a leader in the specialist areas of engineering, computer science, information systems and management, business administration and engineering, media, international business and health. The range of courses and programmes is constantly being extended to take account of innovative developments. The HFU gives particular importance to applied research and technology transfer in cooperation with its partners as an essential catalyst for innovation and a prerequisite for up-to-date teaching. Lecturers are actively involved in application-oriented research, development and project work ensuring the relevance and quality of course content. The HFU strongly supports such activities and resulting publications, thus enabling students and companies to actively participate in research and its results.