

## **InfanDx completes two-year follow-up study AAMBI2 of newborns with suspected perinatal asphyxia**

**Cologne/Germany, 05 November 2020.** InfanDx AG, a diagnostics company specialized in the development of biomarker-based tests, today announced the completion of recruitment for its two-year follow-up study AAMBI2 (Asphyxia Associated Metabolite Biomarker Investigation 2). The study examined the health outcomes of children who might have suffered an oxygen deficit during birth (perinatal asphyxia).

InfanDx is developing the InfanDx HypoxE-test<sup>®</sup> for the rapid and reliable diagnosis of perinatal asphyxia. Affected newborns may develop neonatal encephalopathy, which can lead to brain damage and lifelong disability. There is an effective treatment, hypothermia, which can limit or even completely prevent long-term brain damage. However, this therapy must be initiated within six hours after birth, and many affected infants are not identified in time. Thus, there is a large medical need worldwide for a test to diagnose these newborns rapidly and reliably.

AAMBI was a verification study with more than 110 newborns to confirm metabolite-biomarker combinations that point to oxygen deficit during birth and subsequent brain injury. This data forms the basis of the InfanDx HypoxE-test<sup>®</sup>. For the AAMBI2 study, participants of the original study were evaluated after two years to obtain detailed information on their health outcomes. With a follow-up rate of 93%, the data from the AAMBI2 study may provide a comprehensive and representative clinical picture of the extent of neurological impairment that children with perinatal asphyxia have suffered in the medium term. Thus, the study offers an excellent foundation to further improve the diagnostic and predictive power of the InfanDx HypoxE-test<sup>®</sup>.

Ron Meyer, CEO of InfanDx, said: "With the completion of AAMBI2 and the very high follow-up rate, for the first time we now have an extremely strong data set on the long-term status of our little patients. This will allow a substantial optimization of our test. Our aim is to improve diagnostic options, especially for affected patient groups that are not currently included in clinical risk assessment, and to give more newborns access to a rapid diagnosis and thus, effective treatment. Due to our unique study design, we also expect that this data can help us better understand and detect perinatal asphyxia and its complications in general."

InfanDx will now analyze the patient outcomes and compare them with previously obtained data from their blood samples. Further, the Company expects to gain additional medical insights into perinatal asphyxia and mid-term outcomes, which it plans to publish after final analysis of the data has been completed.

The AAMBI2 study was conducted at four Turkish university hospitals in the cities of Adana, Istanbul, Mersin and Elazig, as there is a higher incidence of perinatal asphyxia in Southeast Europe and Turkey compared to Germany. The initial AAMBI study was carried out at the Life-Science-Inkubator/Bonn, Germany, as part of a project funded by the federal state of North Rhine-Westphalia. The present follow-up study is funded in part by a grant from Germany's Federal Ministry of Education and Research (BMBF).

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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/>