InfanDx AG Reports Successful Validation of Biomarker Panels for the Early Detection of Hypoxic Ischemic Encephalopathy

- Numerous metabolic biomarkers identified in AAMBI study confirmed in BANON cohort
- Panel sensitivities of up to 89% at specificities of up to 93% in blinded validation study
- Formal IVD development of HypoxE® Test progressing on schedule

Cologne/Berlin, Germany, and Boston, MA, USA, October 12, 2022 – InfanDx AG, a privately held diagnostics company focusing on the development and commercialization of novel diagnostic solutions for newborns, today announced that it successfully completed the validation of metabolic biomarker panels for the early detection of Hypoxic Ischemic Encephalopathy (HIE) in newborns. The validated biomarkers of such panels will be the target of the Company’s HypoxE® blood test for the early detection of HIE.

InfanDx, in collaboration with the groups of Prof. Hans-Peter Deigner and Prof. Matthias Kohl at Furtwangen University, had previously identified a number of metabolites that are associated with HIE by comparing metabolite profiles in the blood of newborns with and without HIE in the multicenter AAMBI study with a total of 155 study subjects. Numerous of these individual metabolic biomarkers have now independently been confirmed to distinguish between children with and without HIE enrolled in the BANON study using blood samples taken at birth or shortly thereafter.

The multicenter BANON study with a total of 553 study subjects enrolled at 13 sites predominantly in Germany was closed in May 2022 and focused on studying the population of newborns that are at high risk to develop HIE as indicated by clinical and/or routine blood parameters. The newborns enrolled in BANON were confirmed to either suffer from HIE or not. Such confirmation was based on neurological assessment, amplitude-integrated electroencephalography (aEEG), and/or Magnetic Resonance Imaging (MRI) within days of birth (short-term outcome) and neurodevelopmental assessment at two years of age or older (long-term outcome).

Based on the validated biomarkers, InfanDx designed panels combining top performing biomarkers with the APGAR score at 5 min after birth, a quick test done on every newborn to assess the need for extra medical care. These panels and their interpretive algorithms were optimized by InfanDx on a set of data not part of the validation data set of the BANON study. Algorithms were designed for either umbilical cord blood samples taken at birth or peripheral blood samples taken about two hours after birth in combination with short- and long-term outcome, respectively. In a blinded evaluation, the optimized panels were then validated by Prof. Axel Franz, Principal Investigator and Coordinator of the BANON study, and his group at the University Hospital of Tübingen in collaboration with Prof. Kohl in the independent validation data set of the BANON cohort.

In the blinded validation, the best performing panel demonstrated a sensitivity of 89% at a specificity of 93% for detecting HIE cases as defined by short-term outcome using umbilical cord blood samples. When using long-term outcome as an endpoint, the same algorithm detected HIE cases with a sensitivity of 74% at a specificity of 93%. In both settings, the biomarkers added significantly to the performance of the combined algorithm including the APGAR score. This, on the one hand, reflects the consensus among clinicians that the APGAR score alone is inadequate for detecting HIE, and, on the other hand, confirms research by other groups that it can nevertheless complement biomarker for HIE.
On the back of these results InfanDx will now enter the formal development phase of its HypoxE® Test. The test will be intended as an aid in the early detection and diagnosis of HIE in newborns supporting clinicians in the timely decision to initiate neuroprotective therapies.

To this end, prototype assays for most of the panel biomarkers have already been developed for the Selectra proM Clinical Chemistry Analyzer commercialized by InfanDx’ strategic partner ELITechGroup. Once developed, the HypoxE® Test for Selectra proM will be subjected to a performance evaluation as required by European IVD Regulations (IVD-R) and submitted to a notified body for clearance. The Company expects such submission for the end of 2023. In parallel, InfanDx will work on a version of the HypoxE® Test for point-of-care testing and progress its preparations to perform a study in the US as a basis for a submission for clearance by the US FDA.

“With these data of the BANON study, our efforts to identify novel early biomarkers for HIE yielded first top-line results,” said Prof. Dr. Axel Franz, coordinating Principal Investigator of the BANON study. “It confirms the concept that clinical parameters such as the APGAR score and biomarker information are complementary in a complex condition like HIE. This observation has also been made by other research groups. We expect that the wealth of data provided by AAMBI and BANON will provide us with further important insights into the molecular pathology and clinical dynamics of HIE.”

“I would like to thank our tremendously committed collaborators in Tübingen and Furtwangen and at all the clinical study sites that made these strong results possible,” commented Dr. Achim Plum, CEO of InfanDx. “We will continue working with the scientific and clinical community in HIE to turn these results into a diagnostic product that can aid clinicians in the timely and accurate diagnosis of HIE in newborns that may benefit from neuroprotective therapies.”

“With the biomarkers validated in the BANON cohort, there is now a clear path forward turning these significant results into an IVD product in 2023,” said Dr. Gunter Weiss, COO of InfanDx. “We have the technical expertise in the team, have implemented the required Quality Management System, and with the ELITechGroup a very supportive partner on board to reach this goal in the original timeframe we communicated in early 2021.”

Based on this success in HIE, InfanDx intends to leverage its biomarker and IVD development expertise and capabilities to broaden its pipeline of innovative diagnostic products with the aim of ultimately improving outcomes in neonatal acute and critical care.

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About InfanDx

InfanDx AG is a privately held company focusing on the development and commercialization of novel diagnostic solutions for acute and critical care conditions in newborns.

The Company’s proprietary lead product in clinical development is the InfanDx HypoxE® Test designed for the reliable identification of hypoxic-ischemic encephalopathy (HIE) within the first hours of life. HIE as a consequence of perinatal asphyxia (oxygen deficit during birth) can result in lifelong disabilities. The long-term detrimental effects of HIE can be mitigated and even prevented by neuroprotective hypothermia treatment. However, this therapy must be initiated within six hours after birth to be effective, requiring suitable diagnostic methods to reliably and timely identify the affected newborns. While standard-of-care diagnostic methods cannot deliver a conclusive diagnosis of HIE within this timeframe, the rapid InfanDx HypoxE® Test is designed to support clinicians in the timely decision whether newborns require neuroprotective hypothermia treatment.
The Company is headquartered in Cologne, Germany, with a branch office in Berlin, Germany, and a wholly owned subsidiary in Boston, MA, USA.

For more information, please visit: http://www.infandx.com/

For further information on InfanDx, please contact:

**InfanDx AG**
Nathaly Schaefer, Corporate Affairs Manager  
P: +49 (0) 30 556 535 81  
info@infandx.com

**InfanDx USA, Inc.**  
Jordan deVos (VP Operations)  
contact@infandx-usa.com

**Media contact**

akampion  
Dr. Ludger Wess / Ines-Regina Buth  
Managing Partners  
info@akampion.com  
Tel. +49 40 88 16 59 64 /  
Tel. +49 30 23 63 27 68