Neonatal Diagnostics Company InfanDx AG Completes Two-Year Patient Follow-Up in BANON Study

- *Clinical data curation and evaluation ongoing*
- *Follow-up rate of 77% fully meets expectations (70-80%)*
- *Final HIE biomarker panel validation data expected by end of Q3-2022*

Cologne, Germany, and Boston, MA, USA, May 25, 2022 – InfanDx AG, a privately held diagnostics company focusing on the development and commercialization of novel diagnostic solutions for newborns, announced at an investigator meeting during the recent 48th Annual Meeting of the German Society for Neonatology and Pediatric Intensive Medicine that the clinical 2-year follow-up of patients originally enrolled in the BANON study was formally completed. The study is designed to validate novel diagnostic biomarkers of Hypoxic-Ischemic Encephalopathy (HIE).

The initial BANON study (NCT03357250) enrolled 553 newborns at risk of HIE based on clinical and physiological parameters. To determine the neurological outcome for these babies, a standardized neurological assessment was performed after two years (NCT04714775). This follow-up was now completed with data collected for 425 (77%) of the 553 study subjects in the initial BANON study, thereby fully meeting the expectations (70-80%) of the Company's management.

The multicenter observational study sponsored by InfanDx was conducted at 13 centers in Germany and Turkey. The candidate biomarkers for the panel to be validated were originally discovered in the AAMBI study cohort (NCT03354208/ NCT04714502).

The assessment of the clinical data as well as blinded metabolomic profiling of the blood samples originally collected after birth is ongoing. Once these data sets are complete and curated, predefined data subsets will be used for the optimization and subsequent blinded validation of a metabolic biomarker panel suitable for the reliable detection of HIE within the first hours of life.

The early detection of HIE is critical for the success of cooling therapy (Therapeutic Hypothermia; TH) - the only guideline-recommended therapy to prevent or mitigate adverse neurological outcome in children suffering from HIE. The Company expects validation data for the biomarker panel to be available by end of Q3-2022.

In the meantime, the Company is developing prototypes of targeted in vitro diagnostic assays for the candidate biomarkers identified in the previous AAMBI study that can be implemented on commonly used routine instruments for automated test performance in clinical laboratories and at the point-of-care. Once the final biomarker panel is defined and validated in the BANON study cohort, the Company expects to enter the formal development phase for its HypoxE® Test based on such assays under the European In Vitro Diagnostic Medical Devices Regulation (IVDR). A first IVD product for broad routine use in clinical laboratories is expected for late 2023.

From Q4-2022 onwards, i.e., prior to the launch of an IVD test, the Company expects to enable early adopters with a first generation of the HypoxE® Test based on a similar technology that was used in biomarker discovery for local implementation as laboratory-developed tests (LDT).

"We are very pleased that the BANON follow-up study has been completed within our schedule," said Dr. Gunter Weiss, COO of InfanDx. "The study provides essential clinical data needed for defining and validating the final biomarker panel that will be targeted by our HypoxE Test for the early detection of HIE."

"First of all, I wholeheartedly thank all clinical investigators for their tremendous effort in executing this complex study that is unprecedented in the field," said Dr. Achim Plum, CEO of InfanDx. "Apart from providing us with the data required for validating our HypoxE Test, we expect the study to provide new insights into the clinical representation of HIE at various ages and how we can reliably diagnose this severe condition early enough to implement therapeutic strategies."

The BANON study was coordinated by Prof. Dr. Dr. Peter Bartmann, Head of the Research Group for longitudinal studies at the University of Bonn, Germany, and the Center for Pediatric Clinical Studies (CPCS), an academic full-service Contract Research Organization (CRO) at the University Hospital of Tuebingen, Germany, headed by Prof. Dr. Axel Franz. Metabolomics measurements of the BANON blood samples are performed by the group of Prof. Dr. Hans-Peter Deigner at the Steinbeis Transfer Center for Personalized Medicine at Furtwangen University, Germany. The biostatistical analysis of the data will be performed by Prof. Dr. Matthias Kohl at Furtwangen University, Germany.

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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 life-long 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 time frame, 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/

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