8 December 2023

News Release

FDA Clears First Test to Identify Hospitalized Children at Risk for Acute Kidney Injury (AKI)

One in four children can develop life-threatening kidney injury during hospitalization, making AKI a silent epidemic

COPENHAGEN, DENMARK and BOSTON, Mass., December 8, 2023, The U.S. Food and Drug Administration (FDA) has cleared a new test for assessing acute kidney injury (AKI) in hospitalized children (ages three months through 21 years). Studies show that as many as one in four children are at risk of developing AKI during hospitalization[1], and this is associated with prolonged hospital stays, increased risk of in-hospital death, and future progression to chronic kidney disease.

ProNephro AKI™ (NGAL), developed by BioPorto, is the first biomarker-based test cleared for use in the U.S. for pediatric patients to help doctors identify patients at risk of moderate-to-severe AKI in the intensive care unit (ICU) setting. The test uniquely measures the biomarker neutrophil gelatinase-associated lipocalin, or NGAL, a clinically validated marker of kidney cell damage that studies show[2] can detect AKI days earlier than the current standard of care, which is serum creatinine measurement.

“NGAL has been well studied as a biomarker for kidney cell damage, providing vital information earlier in clinical decision making about what is truly a silent epidemic globally,” said Dr. Prasad Devarajan, BioPorto’s senior medical director and co-discoverer of NGAL. “Widespread NGAL measurement in pediatric settings will give clinicians greater confidence in making treatment decisions, which can save lives, shorten hospital stays and ensure that fewer pediatric patients progress to costly and debilitating chronic kidney disease.”

Outside clinical settings, the short- and long-term impacts of AKI are still underappreciated. An estimated 13 million people worldwide, children and adults, are affected by AKI, resulting in 1.7 million deaths[3]. In addition to causing potentially preventable deaths, undiagnosed or delayed treatment of AKI can lead to chronic kidney disease and end-stage kidney failure, conditions that have significant and long-term costs to society and patients.

"Although the biomarker NGAL has been studied for more than a decade, it has not yet found a place in routine clinical care, making this a significant milestone in pediatric care,” said Stuart L. Goldstein, a pediatric kidney specialist at Cincinnati Children’s Hospital who is an advisor to BioPorto. “Having yet another data point to assess a child’s risk of kidney injury will help physicians make complex and potentially life-saving care decisions earlier and more confidently.”
“As an intensivist, I see firsthand the consequences of undiagnosed AKI in pediatric patients, and that’s what makes a widely available biomarker test for risk of kidney injury such an important step,” said Rajit Basu, an internationally recognized expert in acute kidney injury among critically ill. “It has been too long a wait for a test, given how pervasive and devastating AKI is, but now we finally have a clinical advantage.”

About Acute Kidney Injury
Acute kidney injury is a sudden episode of kidney failure or kidney damage that happens within a few hours or a few days. AKI causes a build-up of waste products in blood and makes it difficult for kidneys to maintain the proper balance of bodily fluids. AKI can also affect other organs such as the brain, heart,

and lungs and is common in patients who are in hospital intensive care units (from American Kidney Association: https://www.kidney.org/atoz/content/AcuteKidneyInjury). For more information about AKI please visit: https://bioporto.com/aki/

About BioPorto
BioPorto is an in vitro diagnostics company focused on saving lives and improving the quality of life with actionable biomarkers – tools designed to help clinicians make changes in patient management. The Company uses its expertise in antibodies and assay development, as well as its platform for assay development, to create a pipeline of novel and compelling products that focus on conditions where there is significant unmet medical need, and where the Company's tests can help improve clinical and economic outcomes for patients, providers, and the healthcare ecosystem.

The Company's flagship products are based on the NGAL biomarker and designed to aid in the risk assessment and diagnosis of Acute Kidney Injury, a common clinical syndrome that can have severe consequences, including significant morbidity and mortality, if not identified and treated early. With the aid of NGAL levels, physicians can identify patients potentially at risk of AKI more rapidly than is possible with current standard of care measurements, enabling earlier intervention and more tailored patient management strategies. The Company markets NGAL tests under applicable registrations including CE mark in several countries worldwide .

BioPorto has facilities in Copenhagen, Denmark and Boston, MA, USA. The shares of BioPorto A/S are listed on the Nasdaq Copenhagen stock exchange. For more information visit www.bioporto.com.