

Aviv Biomedical Announces the New Bilirubin Hematofluorometer

Providing New Opportunities for Detection and Management of Neonatal Jaundice, A Global Unmet Clinical Need

LAKEWOOD, NEW JERSEY, USA, January 11, 2018 /EINPresswire.com/ -- Lakewood, New Jersey, 8 January 2018 – Aviv Biomedical (“Aviv”; www.avivbiomedical.com) announces the launch of a new initiative to identify one or more global partners for commercialisation of its

newest product, the [Bilirubin](#) Hematofluorometer System (AVIV-BHS), for assessment of jaundice in newborn babies.



The AVIV-BHS allows, for the first time, the rapid measurement in neonates of Bilirubin Binding Capacity (BBC), a critical factor in preventing or allowing the development of [neonatal jaundice](#). Bilirubin is neurotoxic, and high levels following birth can result in grave illnesses including seizures, cerebral palsy and kernicterus.

Neonatal jaundice, caused by hyperbilirubinemia, is a common disorder in ~60% of newborns with ~18% of these at risk for neurological disorders or death. All modern hospitals monitor neonatal bilirubin levels (Total Serum Bilirubin or TSB), however, predicting risk solely on TSB levels is known to be inadequate.

The clinical problem addressed by Aviv with the AVIV-BHS instrument is that free bilirubin causes neurological injury in neonates, and not only are bilirubin (TSB) levels important, but also the neonate's ability to bind bilirubin. This is called Bilirubin Binding Capacity (BBC). High TSB and low BBC indicates higher risk. Measuring both parameters improves the accuracy of identifying babies that may need treatment, but this has not been possible up to now. Despite well-established methods and screening protocols developed for full-term (comparatively healthy) babies, current practice is not always ideal, especially for pre-term infants. For these cases, guidelines reduce the thresholds of tolerable TSB. The degree of adjustments is less certain, and physicians are left to their own devices to optimize health care for these babies. There is an increasing realization that the risk factors increase significantly when the levels of bilirubin begin to approach the blood's carrying capacity. Unfortunately, there is no device available that assays this risk.

Infants are released from the hospital as soon as one day after birth, before a potentially damaging spike of bilirubin occurs, so assessment of BBC can play a major preventative role. Rapid tests using the AVIV-BHS for BBC could prevent re-admission in ~10% of affected babies.

Treatments (usually phototherapy or blood transfusion) are expensive and risky, so accurate diagnosis is clinically and economically vital.

BBC has been shown in a comprehensive retrospective analysis to provide improved, clinically

relevant and actionable information. The BBC test using the AVIV-BHS is in a clinical trial at a leading children's hospital. This collaboration is a clinical study of 200 neonates.

Aviv has filed a US patent application for the AVIV-BHS.

The global market size for the AVIV-BHS is estimated at \$2.4 Billion.

The AVIV-BHS provides a functional assay of BBC. It is comprised of (1) a dedicated instrument, computer, sample carrier, bar code reader and (2) a reagent kit of consumables with calibrators and controls. The system exploits the native fluorescence of bound bilirubin. Conventional fluorometers are poorly suited for blood measurements as a right-angle optical path cannot work due to extreme absorption and scattering of light by blood. The AVIV-BHS uses only one surface. Light enters and exits the same surface. It produces results in under 5 minutes, including BBC and Saturation Index (a proxy for free bilirubin).

Aviv is working with The Sage Group to identify a partner with whom it will roll out its ground-breaking AVIV-BHS globally.

Florence Aviv, Aviv's President, stated, "We are delighted to announce the development and forthcoming launch of this ground-breaking new instrument from Aviv, allowing assessment of risk of neonatal jaundice with high accuracy. This is a serious clinical problem in newborn infants and this development from Aviv enables a new approach to assessment of potential development of jaundice, a life-threatening illness occurring at the earliest stages post-birth. This capability should transform neonatal treatment with huge economic benefits for healthcare systems worldwide. Our main priority now is to identify one or more global partners with whom Aviv can work to roll out the AVIV-BHS as widely as possible."

About Aviv Biomedical

Aviv Biomedical ("Aviv") is a leading edge medical instrumentation developer. It was founded in 1971 by the late Jack Aviv in Lakewood NJ USA, initially to service spectrophotometers, circular dichroism spectrometers and spectrofluorometers. The company is a family-owned enterprise run today by the Aviv family.

In 1975, under license from Bell Telephone Research, the company introduced a front surface fluorescence instrument to detect iron deficiency and lead poisoning in whole blood, known as a Zinc Protoporphyrin (ZPP) Hematofluorometer. Over 2,700 instruments have been distributed worldwide, and the product is approved by the US FDA. Aviv is a global leader in development of hematofluorometers and owns proprietary knowledge and IP regarding optimal analytical performance. The AVIV-BHS is the latest instrument in the Company's portfolio.

Since 1971, Aviv Biomedical has strived to provide the best scientific instruments and support possible. The product line includes a ZPP hematofluorometer for whole blood screening for iron deficiency and lead poisoning. Aviv strives to produce an unparalleled medical instrument capability and provide superior service.

About Neonatal Jaundice

Neonatal jaundice is the most common condition in newborns that requires medical attention and hospital readmission. The yellow coloration of the skin and sclera in newborns with jaundice is the result of accumulation of unconjugated bilirubin. In most infants, unconjugated hyperbilirubinemia reflects a normal developmental phenomenon. However, in some infants, serum bilirubin levels may rise excessively. This can be a major cause for concern because unconjugated bilirubin is neurotoxic,

and can cause death in newborns, and lifelong neurologic sequelae in infants who survive (kernicterus). For these reasons, the presence of neonatal jaundice frequently results in diagnostic evaluation. It is particularly prevalent in premature babies. Jaundice can be treated with phototherapy or blood transfusions.

For more information about Aviv Biomedical and partnering opportunities for the AVIV-BHS, please contact:

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