



Innovative biomarkers. Smarter healthcare.

bioMérieux and Astute Medical sign a global agreement to develop and market NEPHROCHECK[®] Test for VIDAS[®], an assay to assess the risk of developing acute kidney injury

Marcy l'Etoile, (France) - San Diego, California (United States) - January 22, 2015 - bioMérieux, a world leader in the field of *in vitro* diagnostics, and Astute Medical, Inc., a company dedicated to improving the diagnosis of high-risk medical conditions and diseases through the identification and validation of protein biomarkers, today announced that they have signed a global, semi-exclusive agreement regarding the development of a test for the early risk assessment of acute kidney injury (AKI). This innovative test, known as the NEPHROCHECK[®] Test, detects the presence of two biomarkers: TIMP-2 (Tissue Inhibitor Metalloproteinases-2) and IGFBP-7 (Insulin-like Growth Factor-Binding Protein-7).

AKI is a major public health threat that is common, costly and potentially fatal in hospitalized patients.¹ Through this worldwide agreement, Astute Medical grants bioMérieux a license to develop, produce and market the NEPHROCHECK[®] Test for use on its immunoassay system range VIDAS[®], miniVIDAS[®] and VIDAS[®] 3.

Today, up to 50% of severely ill patients develop AKI,² which can result in prolonged stays at hospital, especially in intensive care units, thus leading to higher cost of care.³ The guidelines published by the foundation "Kidney Disease Improving Global Outcomes (KDIGO)" recommend that patients be assessed for risk of AKI to protect their kidney function.⁴ Current methods for risk assessment are insufficient, thereby placing substantial numbers of patients at serious risk of complications and death.^{2,5}

Dr. Claudio Ronco of St. Bartolo Hospital in Vincenza, Italy said: "AKI may present the gravest risk for critically ill patients. It is a serious disorder, not only because of its immediate effect on costs and outcomes in the acute setting, but also because of its profound impact on society in the form of devastating and costly chronic kidney disease complications. Expanding access to new predictive tools for AKI risk assessment can help physicians identify and manage patients susceptible to this prevalent, costly and deadly condition."

Commenting on the agreement, Alexandre Mérieux, bioMérieux Chief Executive Officer, said: "The new NEPHROCHECK[®] Test for VIDAS[®] will perfectly complement our high medical value VIDAS[®] assay portfolio. It will help inform clinicians in the management of severely ill patients, including sepsis patients. Deployment of the NEPHROCHECK[®] Test for the VIDAS[®] platform will benefit from the VIDAS[®] installed base of about 29,000 systems and from our complementary large product offering dedicated to diagnosis of severe bacterial infections, in particular with VIDAS[®] B.R.A.H.M.S. PCT[™]. With this new assay, bioMérieux will reinforce its leading position in the risk assessment and diagnosis of patients in an emergency situation, including those with sepsis and high risk of severe medical complications."

Chris Hibberd, Astute Medical Chief Executive Officer, added: "This agreement aligns with our business strategy of bringing novel biomarkers with high clinical value to market through a variety of testing platforms. This is great news for customers as it will increase global market availability and offer a range of platform capabilities to suit laboratory needs."

To validate TIMP-2 and IGFBP-7 as biomarkers for AKI risk assessment, Astute analyzed the biomarkers in two rigorous company-sponsored, multicenter, observational clinical studies. In these studies, the NEPHROCHECK[®] Test identified the majority of patients manifesting moderate or severe AKI within 12 hours of assessment.^{6,7}

ABOUT BIOMERIEUX

Pioneering diagnostics

A world leader in the field of *in vitro* diagnostics for 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2014, revenues reached €1,698 million with 88% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the NYSE Euronext Paris market (Symbol: BIM - ISIN: FR0010096479).
Corporate website: www.biomerieux.com. Investor website: www.biomerieux-finance.com.

ABOUT ASTUTE MEDICAL, INC

Named by the Wall Street Journal as one of the Top 10 Healthcare Start-Ups of 2012, Astute Medical is dedicated to improving the diagnosis of high-risk medical conditions and diseases through the identification and validation of protein biomarkers that can serve as the basis for novel diagnostic tests. The Company's focus is community and hospital-acquired acute conditions that require rapid diagnosis and risk assessment. Astute Medical's current areas of interest include abdominal pain, acute coronary syndromes, cerebrovascular injury, kidney injury and sepsis.

Astute Medical's NEPHROCHECK[®] Test received 510(k)-clearance through the FDA's *de novo* classification process in September 2014. The test was CE-marked in 2012 and is available in Europe.

For information regarding trademarks and other intellectual property applicable to this product, including international trademarks, please see AstuteMedical.com/About/IntellectualProperty. PN 0418 Rev A 2015/01/14

CONTACTS

Investor Relations

bioMérieux

Isabelle Tongio
Tel: + 33 4 78 87 22 37
investor.relations@biomerieux.com

Media Relations

bioMérieux

Aurore Sergeant
Tel: + 33 4 78 87 54 75
media@biomerieux.com

Image Sept

Laurence Heilbronn
Tel: + 33 1 53 70 74 64
lheilbronn@image7.fr

Claire Doligez
Tel: + 33 1 53 70 74 48
cdoligez@image7.fr

Astute Medical

Nadine Padilla
LawPadilla Communications
Tel: +1 (619) 507-9306
nadine@lawpadilla.com

¹ Lewington AJP, Cerdá J, Mehta RL [Raising Awareness of Acute Kidney Injury: A Global Perspective of a Silent Killer.](#) *Kidney Int.* 2013;84(3):457-467.

² Mandelbaum T, Scott D, Lee J, et al. [Outcome of Critically Ill Patients with Acute Kidney Injury Using the AKIN Criteria.](#) *Crit Care Med.* 2011;39(12):2659–2664.

³ Dasta JF et al. Costs and outcomes of acute kidney injury (AKI) following cardiac surgery. *Nephrol Dial Transplant.* 2008;23(6):1970-4.

⁴ Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney Inter., Suppl.* 2012; 3:1-150.

⁵ MacLeod A. NCEPOD report on acute kidney injury – must do better. *Lancet.* 2009;374:1405-6.

⁶ Kashani et al. Discovery and validation of cell-cycle arrest biomarkers in human acute kidney injury. *Critical Care* 2013, 17:R25.

⁷ Bihorac A, et al. Validation of Cell-Cycle Arrest Biomarkers for Acute Kidney Injury Using Clinical Adjudication. *Am J of Respir Crit Care Med.* 2014;189(8):932-939.