New Study Shows Urinary Levels of Novel Biomarkers Measured by Astute Medical’s Nephrocheck® Test are Associated with Adverse Long-Term Outcomes in Patients with Acute Kidney Injury

SAN DIEGO – January 13, 2015 -- Citing a study recently published online in the Journal of the American Society of Nephrology (JASN), Astute Medical, Inc. Co-founder and Chief Scientific Officer Paul McPherson today said the Company's investment in clinical studies continues to yield new information about the novel acute kidney injury (AKI) biomarkers measured by the Nephrocheck® Test.

Investigators in the blinded, international, multi-center study found that the combination of the two biomarkers tissue inhibitor metalloproteinase-2 (TIMP-2) and insulin-like growth factor binding protein-7 (IGFBP-7) measured early in the setting of critical illness are associated with increased risk for mortality or receipt of renal replacement therapy over the next 9 months in patients with AKI. The combination of the two biomarkers remained significantly associated with the composite endpoint after accounting for serum creatinine, a common lab test that measures kidney function. 1

Investigators also found that the risk of dialysis or death increased with higher levels of the biomarker combination. 1

The authors noted in the publication that the results suggest that the association of the biomarkers of acute kidney distress and long-term adverse outcomes is caused by important underlying renal biology. 1

The Company-sponsored study enrolled 744 critically ill patients, with 52 excluded from the analyses, at 35 medical centers in North America and Europe. Patients were tested within the first day of admission to the intensive care unit. The combination of TIMP-2 and IGFBP-7 was measured with Astute Medical’s Nephrocheck® Test. 1

The Nephrocheck® Test was cleared through the FDA’s de novo classification process in September 2014 and is CE-marked in Europe. In the United States the Nephrocheck® Test is only cleared for use in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are intensive care unit (ICU) patients as an aid in the risk assessment for moderate or severe AKI within 12 hours of patient assessment. This clearance does not include use of the Nephrocheck® Test for the type of patient assessment performed in the study reported in the JASN article.

To facilitate marketing of the Nephrocheck® Test in the United States and Europe, in July 2014, Astute designated Ortho-Clinical Diagnostics, Inc. (OCD) as the exclusive sales agent for Astute’s Nephrocheck® Test and Astute140® Meter in certain countries of the European Union and the United States. Astute has also granted OCD a semi-exclusive worldwide license to develop and commercialize a version of the Nephrocheck® Test for use on its VITROS® line of automated, high-volume testing platforms. The test developed for the OCD platform will require separate regulatory clearances before it can be sold.

AKI, an emerging global health threat, is a common, costly and potentially deadly complication in hospitalized patients. 2 Traditional methods of risk assessment are insufficient placing substantial numbers of patients at serious risk of complications and death. 3,4 AKI may affect up to 50 percent of critically ill hospitalized patients. 5

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