FOR IMMEDIATE RELEASE

Media Contacts
Baxter: Andrea Johnson, (224) 948-5353
media@baxter.com
bioMérieux: Romain Duchez, +33 (0)4 78 87 21 99
media@biomerieux.com

Investor Contacts
Baxter: Clare Trachtman, (224) 948-3020
bioMérieux: Franck Admant, +33 (0)4 78 87 20 00
investor.relations@biomerieux.com

BAXTER AND BIOMÉRIEUX ANNOUNCE CE MARK FOR NEPHROCLEAR™ CCL14 TEST TO PREDICT PERSISTENT SEVERE ACUTE KIDNEY INJURY

- *Reinforces Baxter and bioMérieux's shared commitment to enhancing acute kidney injury (AKI) management through informed clinical decision-making and patient-centered approaches*
- *Aids hospitals in optimizing critical care resources by helping anticipate appropriate level of care for AKI patients*
- *Research suggests CCL14 is the most predictive biomarker of persistent severe AKI when compared with other AKI biomarkers*

DEERFIELD, Ill., AND MARCY L'ETOILE, FRANCE, OCTOBER 21, 2021 – Baxter International Inc. (NYSE:BAX), a global leader in acute care, and bioMérieux (EPA:BIM), a global leader in *in vitro* diagnostics, today announced the CE marking of the **NEPHROCLEAR™ CCL14** Test. The **NEPHROCLEAR™ CCL14** Test is designed to predict persistent severe acute kidney injury (PS-AKI) and can be used to support timely clinical decision-making and care pathways. The companies intend to commercially launch the **NEPHROCLEAR™ CCL14** Test in western Europe in 2022.

"Baxter is proud to partner with bioMérieux to offer the **NEPHROCLEAR™ CCL14** Test as an important new diagnostic option to support individualized AKI management that gives every patient the greatest opportunity for recovery," said Reaz Rasul, general manager of Baxter's Acute Therapies business. "We remain committed to advancing purposeful innovation across the care continuum to help reduce complexity and enable efficiencies in critical care, especially as hospitals continue to feel the impact of the COVID-19 pandemic."

"This new step in our collaboration with Baxter further strengthens our innovative diagnostics solutions portfolio for the management of AKI," said Pierre Boulud, chief operating officer, clinical operations, bioMérieux. "True to our public health mission, we bring to the medical community this high-medical-value immunoassay that has the potential to change the current strategy of care for patients suffering from AKI."

AKI is a sudden decrease in kidney function over a period of hours to days, often as a result of illness, trauma or infection. The sudden loss of kidney function leads to the accumulation of toxins and fluid in the blood that, if left untreated, may lead to death. Baxter recently collaborated with bioMérieux and Premier Applied Sciences® (PAS) to conduct a study assessing the economic and clinical impact of PS-AKI. Data from this study presented at the International Symposium on Intensive Care and Emergency Medicine (ISICEM) showed that PS-AKI (stage 3 AKI lasting ≥ 3 days) is independently associated with a longer length of stay and higher costs during index hospitalization and 30-day follow-up compared to non-persistent AKI. Additional data from this study, presented at the European Society of Intensive Care Medicine (ESICM) LIVES congress, showed that PS-AKI is prevalent among hospitalized adults in the U.S. and is associated with a significantly higher risk of death during hospitalization, as well as readmissions, dialysis and death during 30-day follow-up, compared to patients without PS-AKI.

A consensus statement from the Acute Disease Quality Initiative Consensus Conference underscores the importance of new biomarkers like CCL14 (C–C motif chemokine ligand 14), the biomarker measured by the **NEPHROCLEAR™ CCL14** Test, in helping to manage AKI by identifying high-risk patient groups, guiding therapy and improving care pathways.[1] Recent studies published in *Intensive Care Medicine*,[2] *Critical Care*[3] and *Journal of Thoracic and Cardiovascular Surgery*[4] suggest that CCL14 is the most predictive biomarker of PS-AKI when compared with other AKI biomarkers, including NGAL, CHI3L1, L-FABP, Cystatin C, Proenkephalin, and KIM-1.

The **NEPHROCLEAR™ CCL14** Test provides a reliable and precise measurement to help clinicians assess an individual patient's risk for developing PS-AKI. The test's area under the receiver operating characteristic curve (AUC), which is an indicator of the overall accuracy of a diagnostic test, is 0.82, illustrating the CCL14 biomarker's ability to distinguish patients who will likely develop PS-AKI from those who will not.[2, 5] The test results can help clinicians determine personalized treatment approaches for each patient, including level of care and the need for appropriate interventions,

based on KDIGO (Kidney Disease Improving Global Outcomes) clinical practice guidelines.[3, 5, 6] When test results show a patient is at increased risk for PS-AKI, they may be triaged to a higher level of care to help mitigate potential complications of AKI.[2, 3]

Baxter and bioMérieux previously announced an agreement to develop and distribute this novel AKI biomarker test to assess the risk of PS-AKI and support clinical decision-making in AKI management. Both companies will provide support at the customer site for the **NEPHROCLEAR™ CCL14** Test, while bioMérieux retains control over the regulatory approval process and Baxter retains control over the commercialization strategy. Baxter is bioMérieux's exclusive distributor of the **NEPHROCLEAR™ CCL14** Test in Europe and will also be the exclusive distributor in the U.S. pending clearance from the U.S. Food and Drug Administration (FDA).

CE-Marked Intended Purpose/Important Safety Information for the NEPHROCLEAR™ CCL14 Test

The **NEPHROCLEAR™ CCL14** Test is an automated immunofluorescence assay for use on the ASTUTE140® Meter for the quantitative measurement of CCL14 (C-C motif chemokine ligand 14) in human urine.

The **NEPHROCLEAR™ CCL14** Test is intended to be used in conjunction with clinical evaluation in adult patients who are in the hospital for an acute illness or condition and have moderate or severe (Stage 2 or 3) acute kidney injury (AKI) as an aid in the risk assessment for developing persistent severe AKI (Stage 3 AKI lasting ≥ 72 hours) within 48 hours of patient assessment.

Rx Only. For safe and proper use of the products mentioned herein, please refer to the Operator's Manual or Instruction for Use.

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

About bioMérieux

Pioneering Diagnostics

A world leader in the field of in vitro diagnostics for over 55 years, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2020, revenues reached €3.1 billion, with over 90% of international sales (outside of France).

bioMérieux provides diagnostic solutions (systems, reagents, software and services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286.
Reuters: BIOX.PA/Bloomberg: BIM.FP.
Corporate website Investor website

*This release includes forward-looking statements concerning the **NEPHROCLEAR™ CCL14** Test, including potential benefits associated with the product. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: demand for and market acceptance for new and existing products; product development risks; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of natural disasters, public health crises and epidemics/pandemics, regulatory actions or otherwise); satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities (including potential FDA clearance of the **NEPHROCLEAR™ CCL14** Test); product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

###

[1] Ostermann M, Zarbock A, Goldstein S, et al. Recommendations on Acute Kidney Injury Biomarkers From the Acute Disease Quality Initiative Consensus Conference: A Consensus Statement. JAMA Netw Open. 2020;3(10):e2019209. doi:10.1001/jamanetworkopen.2020.19209

[2] Hoste E, Bihorac A, Al-Khafaji, A, et al. Identification and validation of biomarkers of persistent acute kidney injury: the RUBY study. Intensive Care Med 46, 943–953 (2020). https://doi.org/10.1007/s00134-019-05919-0

[3] Bagshaw, S.M., Al-Khafaji, A., Artigas, A. et al. External validation of urinary C–C motif chemokine ligand 14 (CCL14) for prediction of persistent acute kidney injury. Crit Care 25, 185 (2021). https://doi.org/10.1186/s13054-021-03618-1

[4] Massoth C, et al. Comparison of C-C motif chemokine ligand 14 with other biomarkers for adverse kidney events after cardiac surgery. J Thorac Cardiovasc Surg. 2021 Mar 10:S0022-5223(21)00436-0. doi: 10.1016/j.jtcvs.2021.03.016

[5] BioMerieux NephroClear CCL14 Test Kit Package Insert

[6] International Society of Nephrology. (2012) KDIGO Clinical Practice Guideline for Acute Kidney Injury. Kidney Int. Suppl.2, 1-138. http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO%20AKI%20Guideline.pdf