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BAXTER ANNOUNCES RESULTS OF CLINICAL TRIAL ON BENEFITS OF DYNAMIC FLUID MANAGEMENT IN SEPTIC SHOCK PATIENTS

Results published in CHEST Journal demonstrate benefits of using dynamic measures to guide fluid therapy decisions

DEERFIELD, Ill., MAY 6, 2020 – Baxter International Inc. (NYSE:BAX), a leader in innovative technology for medication delivery, today announced results of the Fluid Responsiveness Evaluation in Sepsis Hypotension and Shock (FRESH) study using the **Starling** Fluid Management Monitoring System, recently published in CHEST. Performed at 13 hospitals across the United States and United Kingdom, the FRESH study demonstrates lower net fluid balance, reduced mechanical ventilation and reduced kidney injury in septic shock patients when a non-invasive dynamic assessment is used to guide intravenous (IV) fluid and vasopressor administration.

Septic shock is a common, life-threatening condition that can develop due to a bacterial or viral infection, including respiratory viruses like influenza or SARS-CoV-2. Every year, it affects an estimated 47 million people globally and results in at least 11 million deaths. A cornerstone of treating patients with septic shock is IV fluid therapy. However, IV fluid therapy requires a delicate balance, as volume overload in septic patients is associated with negative patient outcomes, such as sepsis-associated organ failure and increased need for mechanical ventilation.[1,2,3]

"This study demonstrates that by using a shock resuscitation protocol guided by dynamic fluid response measurement technology, we can better identify patients who will likely be helped with IV fluid therapy," said Ivor Douglas, M.D., Denver Health Medical Center and primary investigator of the FRESH Study. "By identifying these patients and individualizing treatment, the FRESH study

builds on other literature showing benefits associated with dynamically assessing fluid responsiveness."

The FRESH study is the first randomized controlled clinical trial to demonstrate the benefits of performing Passive Leg Raises (PLR) to assess fluid responsiveness and personalize the use of fluids and vasopressors for shock resuscitation. Patients who entered study sites with sepsis-associated hypotension (low blood pressure) and anticipated ICU admission were randomly selected for the intervention arm or control arm. Participants in the intervention group were assessed for fluid responsiveness by performing a PLR using Baxter's Starling Fluid Management Monitoring System before any clinically driven fluid bolus or increase in vasopressors, which are drugs used to constrict the blood vessels and raise blood pressure, were administered. If the patient demonstrated fluid responsiveness, fluid bolus was administered. If the patient did not demonstrate fluid responsiveness, other vasopressors were considered as alternatives. In both cases, PLRs were performed repeatedly for continuous fluid management. Patients in the control group received usual care.

The study's objective was to assess the mean difference in fluid balance at 72 hours or ICU discharge, whichever came first, and associated secondary patient outcomes. The analysis included 83 patients in the intervention arm and 41 in the control arm, finding positive fluid balance at 72 hours or ICU discharge was significantly lower in the intervention group (-1.37L, with 0.65 ± 2.85L intervention arm vs. 2.02 ± 3.44L usual care, p=0.021). A lower fluid balance reflects a decreased administration of excessive fluid.

"The approach outlined in the FRESH study enables clinicians to gauge the effectiveness of IV fluid before it's given, making more informed and personalized decisions to administer when appropriate," said David Ferguson, general manager of Baxter's Medication Delivery business. "The study's findings are important in validating our efforts to advance specialized patient monitoring in pursuit of improved patient outcomes."

The FRESH study also assessed several pre-defined and exploratory secondary endpoints, finding significantly fewer patients required renal replacement therapy (5.1% vs. 17.5%, p=0.04) or mechanical ventilation (17.7% vs. 34.1%, p=0.04) in the intervention arm compared to usual care. Additionally, significantly greater intervention group patients were discharged home (63.9% vs. 43.9%, p=0.035), as opposed to in-hospital mortality or being discharged to hospice or a

rehabilitation facility. Safety endpoints were comparable between intervention and control arms, with no statistical differences in mortality, treatment emergent serious adverse events, nor rates of hospital discharge without ICU readmissions. No statistical differences were observed in hospital and ICU lengths of stay.

Physiologically informed fluid and vasopressor resuscitation using PLR-induced stroke volume change may have treatment implications for patients with COVID-19 and associated shock symptoms. Recent guidelines by the World Health Organization suggest considering dynamic indices of volume responsiveness, including passive leg raises, to guide volume administration for patients with a suspected COVID-19 infection, as fluid resuscitation may lead to volume overload.[4]

Starling is currently approved in more than 30 markets globally.

About Starling

Brought to Baxter through the Cheetah Medical acquisition in 2019, the Starling system is a completely non-invasive fluid management monitoring system that provides clinicians with a dynamic assessment of fluid responsiveness quickly, accurately and precisely. Starling can be used across many care settings within the hospital to help determine whether fluid administration will be effective, enabling clinicians to personalize fluid therapy. Baxter is investing in specialized patient monitoring as part of its efforts to enable personalized therapy and eliminate preventable harm.

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 more than 85 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.

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This release includes forward-looking statements concerning the results of the FRESH trial and Starling, including potential benefits associated with its use. 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: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; 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.

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