Study Demonstrates the Potential of HelixBind's RaPID/BSI Assay to Accurately Identify Bloodstream Infections Associated with Sepsis in Patients Undergoing Antimicrobial Treatment

BOXBOROUGH, Mass. – February 12, 2024 - HelixBind, Inc., a developer of *in-vitro* diagnostic products for the characterization of invasive infections, announced the publication of a peer-reviewed study demonstrating the capability of the company's RaPID/BSI assay to accurately identify bloodstream infections associated with sepsis direct from blood, even in the presence of antimicrobial treatment. The study, published in the Journal of Clinical Microbiology titled, "Culture-independent identification of bloodstream infections from whole blood: prospective evaluation in specimens of known infection status," was conducted at Tufts Medical Center in Boston, Mass.

"HelixBind's RaPID/BSI is a molecular diagnostic assay that can identify pathogens that cause sepsis within a few hours from patient presentation, unlike the standard of care which often takes days due to the requirement for blood cultures," said Alon Singer, Ph.D., CEO of HelixBind. "In this study, the Investigators demonstrated that RaPID/BSI is not prone to false positive results, which is common with assays that rely on sequencing or standard molecular diagnostic techniques. Importantly, they also demonstrated that the assay can detect ongoing infections missed by follow-up cultures. We are confident that this capability will provide physicians with the crucial information necessary to guide personalized antimicrobial therapy enabling improved patient management and antimicrobial stewardship."

The study examined the performance of HelixBind's RaPID/BSI test in two independent cohorts, one comprising subjects assumed to be bloodstream infection/sepsis negative and another comprising subjects with a known bloodstream infection with ongoing antimicrobial treatment. The investigators concluded:

- RaPID/BSI remained effective despite the presence of antimicrobials in the blood, a well-established confounding substance-class reducing the sensitivity of standard of care diagnostics.
- RaPID/BSI correctly identified 58% more ongoing infections in patients with concurrent antimicrobial therapy than follow-up blood cultures.
- The proprietary approach to sample-preparation incorporated in RaPID/BSI resulted in a very low false-positivity rate, far below standard molecular diagnostic approaches, demonstrating that positive results are clinically meaningful.

The corresponding author of the study is Vidya Iyer, MBBS, previously at Tufts Medical Center and currently Executive Director of Operations and Finance in the Division of Clinical Research for Massachusetts General Research Institute.

About HelixBind

HelixBind, Inc. is a developer and manufacturer of *in-vitro* molecular diagnostic products. The company's proprietary RaPID (Resistance and Pathogen IDentification) platform enables direct-from-specimen characterization of invasive infections such as bloodstream infections (BSIs) associated with sepsis. The first test for the platform, RaPID/BSI, provides species level information across a broad, 20-target, test menu directly from patient blood in about four hours. Unlike all culture-based tests, RaPID/BSI is not confounded by polymicrobial infections or ongoing antimicrobial treatment; crucial for accurately diagnosing high-risk patients who are often already on antibiotics. The RaPID platform and RaPID/BSI were designated as a Breakthrough

Device by the U.S. Food and Drug Administration. Learn more at www.helixbind.com and follow us on LinkedIn.

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