PRESS RELEASE

FDA Grants HelixBind Breakthrough Device Designation for the RaPID Sepsis Test

HelixBind's device identifies the most common bloodstream infections associated with sepsis direct from blood and is designed to reduce time-to-diagnosis from days to hours

Boxborough, MA – August 24, 2020 – HelixBind, which is developing an innovative diagnostic platform to revolutionize care for invasive infections such as sepsis, announced today it has been awarded the Breakthrough Device Designation from the FDA for RaPID/BSI, the first test for its RaPID platform.

RaPID is HelixBind's direct-from-blood platform for the identification and characterization of bloodstream infections. RaPID/BSI identifies the most common bloodstream infections associated with sepsis.

The FDA's Breakthrough Devices Program is reserved for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients receive more timely access to these medical devices by expediting their development, assessment and review by the FDA.

HelixBind's submission to the FDA focused on the features of the RaPID platform that distinguish the test from the current standard of care, and meet the criteria for the breakthrough designation: the fast turnaround time of a few hours, the large panel of twenty-one bacterial and fungal pathogens covered by a single test, and the high sensitivity of the test to identify very small concentrations of pathogens contained within a blood specimen.

Sepsis, caused by a severe immune response to a bloodstream infection, is a major global health crisis. Every year in the US there are 1.7M cases and more than 270,000 of those patients

will not survive. Prognosis for septic patients deteriorates hourly, so fast and accurate identification and characterization of the infection is crucial to assist physicians to initiate the appropriate antimicrobial treatment as soon as possible.

HelixBind's RaPID/BSI can provide unequivocal identification of bloodstream infections direct from blood within hours (versus days with current methods). This can help with the selection of appropriate antimicrobial treatment. Ensuring that patients receive the right antimicrobial to treat their infection is critical to improving care and outcomes, reducing antimicrobial resistance, and decreasing cost to the healthcare system.

"We are thrilled to receive the Breakthrough Device Designation as it is strong validation of the work we are doing at HelixBind," said Alon Singer, CEO of HelixBind. "We look forward to continuing our dialogue with the FDA and following its guidance to ensure RaPID/BSI is safe and effective, significantly improving the lives of countless individuals afflicted with sepsis."

About HelixBind, Inc

HelixBind is developing an innovative diagnostic platform to revolutionize care for invasive infections such as sepsis. Its novel platform provides faster, more accurate, and more informative microbiology results, assisting clinicians in precisely identifying bloodstream infections and developing personalized antimicrobial interventions for infected patients. This approach can improve outcomes, save lives, and reduce the spread of antimicrobial resistance. Learn more at www.helixbind.com.

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