IDbyDNA and Rady Children's Institute for Genomic Medicine Partner on Clinical Trial for the Identification of Pediatric Central Nervous System Infections

IDbyDNA's Explify® platform will be used to analyze pathogens and immune reaction in cerebrospinal fluid of pediatric patients

SALT LAKE CITY and SAN DIEGO, Oct. 3, 2018 — The Rady Children's Institute for Genomic Medicine (RCIGM) and IDbyDNA, a metagenomics technology company translating microbial genomics into actionable information for healthcare providers, have launched a clinical trial to improve diagnostics for pediatric central nervous system (CNS) infections.

The trial, titled PIPSEC – Pediatric Infectious disease Precision medicine using Sequencing Evaluation of CSF, will evaluate IDbyDNA's next generation sequencing and analysis platform, Explify, for its diagnostic capabilities in the field of pediatric CNS infections.

"Diagnosing children who present with symptoms of CNS infection is both complex and extremely time sensitive. It is essential for physicians to have access to solutions that will not only provide pathogen ID quickly, but will also inform them if the symptoms arise from an infection or from an autoimmune disease," said Stephen Kingsmore, M.D., D.Sc., President and CEO of the Institute.

"Having such a platform that can analyze all aspects simultaneously would be a game changer, which is why we are excited to work with IDbyDNA to potentially help making this test a part of the standard of care," he added.

In the trial, excess cerebral spinal fluid (CSF) samples collected from children for diagnosis will be analyzed using the Explify Platform, with the results compared to standard of care. All actionable information will be acted upon according to the judgement of the specific site principal investigator (PI) and the study PI, Lauge Farnaes, M.D., Ph.D.

The analysis is based on next generation sequencing (NGS) of the sample and the comparison of the results to a database containing over 50,000 microorganisms and over 3,000 pathogens. In addition, the platform analyzes both DNA and RNA in the same sample and provides information on both the microbial content in the sample as well as the patient's immune response.

"The Explify platform is unique in that it can analyze many types of samples and detect all types of pathogens including bacteria, viruses, fungi and parasites. It is not only unbiased in pathogen detection, but actually unbiased toward sample source," said Guochun Liao, Ph.D., IDbyDNA's Founder, President & Chief Executive Officer.

"These capabilities allow us to quickly and efficiently move into new areas of microbial profiling and pathogen detection and form collaborations with both hospitals and clinical laboratories regardless of their specialty," he added. "The team at RCIGM is world renowned for their advanced genomics diagnostics, and we are proud to be collaborating with them. Most importantly, we are looking forward to possibly helping sick children by finding the exact cause of their disease."

Lauge Farnaes, M.D, Ph.D., the Institute's Assistant Medical Director and the study PI added, "Children admitted with symptoms of CNS infection can easily be misdiagnosed and given the wrong treatment. These symptoms can arise from an infection, whose source is often hard to detect, or from an immune response not related to infection.

"Unfortunately, the treatments are completely different, and without the right diagnosis physicians may end up worsening the case. The promise of the Explify Platform is that it can detect both the origin of the disease, be it infection or the immune system, and when it is a pathogen, the platform is able to detect the exact pathogen to inform of further treatment steps."

About PIPSEC - Pediatric Infectious disease Precision medicine using Sequencing Evaluation of CSF
PIPSEC is a prospective, multi-site, study to evaluate the clinical utility and application of DNA and RNA next generation sequencing of CSF samples for identification of pathogens directly in pediatric patients with suspected CNS infections. The trial will be conducted at three sites across the United States (Rady Children's Hospital in San Diego, Children's Hospital of Orange County and Nicklaus Children's Hospital in Miami). Diagnostic rate and clinical utility of concurrent standard testing will be compared to the diagnostic rate and clinical utility of the Explify DNA and RNA sequencing results.
The study enrollment period will last up to 24 months.

About Rady Children's Institute for Genomic Medicine
The Institute is leading the way in advancing precision healthcare for infants and children through genomic and systems medicine research. Discoveries at the Institute are enabling rapid diagnosis and targeted treatment of critically ill newborns and pediatric patients at Rady Children's Hospital-San Diego and partnering hospitals. The vision is to expand delivery of this integrated translational research process to enable the practice of precision pediatric medicine at children's hospitals across California, the nation and the world. RCIGM is a subsidiary of Rady Children's Hospital and Health Center. Learn more at www.RadyGenomics.org. Follow us on Twitter and LinkedIn.

About Rady Children's Hospital-San Diego
Rady Children's Hospital-San Diego is a 524-bed pediatric care facility providing the largest source of comprehensive pediatric medical services in San Diego, southern Riverside and Imperial counties. Rady Children's is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare and is the region's only designated pediatric trauma center. In June 2018, *U.S. News & World Report* ranked Rady Children's among the best children's hospitals in the nation in all ten pediatric specialties the magazine surveyed. Rady Children's is a nonprofit organization that relies on donations to support its mission. For more information, visit www.rchsd.org and find us on Facebook, Twitter and Vimeo.

About Explify
The Explify Platform simultaneously profiles tens of thousands of microorganisms and pathogens in any sample to deliver actionable information to healthcare providers. This turn-key solution enables clinical

laboratories to offer NGS-based metagenomics testing for infectious disease. From sample preparation to report delivery, the Explify Platform manages laboratory workflow, analyzes metagenomics data, and provides applications for clinical review, quality control and reporting. The Explify Platform offers clinical laboratories a streamlined path to offering unbiased, NGS-based Infectious Disease tests that are more comprehensive, and more accurate than conventional tests. Explify metagenomics analysis is a proprietary DNA & RNA search engine that analyzes tens of millions of Next-Generation Sequencing reads within minutes to enable the detection of tens of thousands of microorganisms. The proprietary Explify database includes millions of curated DNA and RNA reference sequences and can identify more than 50,000 microorganisms and over 3,000 known common and rare pathogens.

About IDbyDNA

IDbyDNA has developed transformative metagenomics technology to simultaneously profile tens of thousands of microorganisms and pathogens in any sample. Our turn-key Explify Platform easily integrates into medical laboratories to deliver actionable information to healthcare providers. Working with our global partners, we are setting the standard for the identification and understanding of microorganisms and their role in human health. http://www.idbydna.com/

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