KEYPROTEO

Key Proteo Submits *De Novo* Application to FDA for its First Newborn Screening Kit

Potential to be the first IVD for the screening of Wilson Disease, Wiskott-Aldrich Syndrome, X-linked Agammaglobulinemia and Adenosine Deaminase Deficiency

SEATTLE, WA – March 29, 2024 – Key Proteo, a pioneering proteomics diagnostics company specializing in the enhanced early detection of rare but treatable genetic disorders, today announced that it has submitted a *de novo* classification request to the U.S. Food and Drug Administration (FDA) for its first *in vitro diagnostic* Key Proteo Newborn Screening Kit. The novel proteomics-based screening panel addresses a critical, unmet need to aid in the early identification of four treatable rare genetic disorders that current newborn screening programs do not typically test for, including Wilson Disease (WD), Wiskott-Aldrich Syndrome (WAS), X-linked Agammaglobulinemia (XLA) and Adenosine Deaminase Deficiency (ADA). Early screening has the potential to enable timely intervention that can help change the clinical trajectory and relieve the burden of disease for patients and their families afflicted by these potentially devastating disorders.

The submission of Key Proteo's Newborn Screening Kit 1 comes after screening over 22,000 newborn samples in an ongoing pilot study. Subsequently, Key Proteo successfully completed a clinical study that included 4,690 newborn samples analyzed at 3 sites across North America. "We are excited to lead the charge towards changing the clinical course of treatable rare genetic disorders that are currently being missed," said Mark Willig, President and CEO of Key Proteo. "Enhanced early screening is key to enabling clinical interventions that can significantly help reduce morbidity and mortality. I am extremely proud of the tireless efforts that our team has made over the past five years to reach this important milestone not just for our company, but for the patients and their families that will benefit from these life-altering screening tools."

With its initial focus on addressing unmet needs for WD, WAS, XLA and ADA in the newborn screening space, nearly 100 treatable genetic disorders have been identified that could potentially be adapted to Key Proteo's dynamic proteomics-based platform. The *in vitro diagnostic* Key Proteo Newborn Screening Kit 1 will only be available for commercialization once the FDA has completed its process. Currently, Key Proteo Newborn Screening Kit 1 is available as an RUO offering.

In parallel path, Key Proteo is also expanding its operations to include a CLIA-certified laboratory to serve unaddressed newborn screening needs among public health laboratories, reference laboratories, hospital

laboratories and other providers associated with neonatal care that may prefer to send-out for these and other critically important newborn screening tests.

ABOUT WILSON DISEASE, WISKOTT-ALDRICH SYNDROME, XLA and ADAD

Wilson Disease, affecting approximately 1 in 30,000 individuals, is characterized by excess copper accumulation in the liver, brain, and eyes, and can lead to liver disease, central nervous system dysfunction and death. Timely diagnosis and treatment are vital to prevent long-term disability and life-threatening complications.

Impacting 1 in 100,000, Wiskott-Aldrich Syndrome is characterized by immunodeficiency and impaired blood clotting. Symptoms include bruising, susceptibility to infections and immune and inflammatory disorders, and heightened cancer risk. Eczema often accompanies the syndrome. WAS patients face increased vulnerability to infections, bleeding, and cancers, often leading to premature mortality.

X-linked Agammaglobulinemia, impacting around 1 in 250,000 individuals, mainly males, is marked by severely low immunoglobulin levels. Typically, symptoms manifest as recurrent bacterial infections from around 6 months of age, with commonly diagnosed infections including lung, ear, sinus, eye, and skin infections, along with those linked to chronic diarrhea.

Adenosine Deaminase Deficiency (ADA), impacting roughly 1 in 500,000 individuals, is a primary cause of severe combined immunodeficiency (SCID), impairing the body's ability to combat infections. Symptoms typically emerge before 6 months, ranging from pneumonia to chronic diarrhea and delayed development. While most symptoms surface early, some may manifest later in life.

ABOUT KEY PROTEO

Key Proteo is on a mission to save lives and relieve the burden of disease for patients and their families afflicted by rare but treatable genetic disorders through early screening. Many treatable genetic disorders are difficult to detect, but when found early, intervention can be enabled to help change the clinical course. With its initial focus on newborns, Key Proteo’s dynamic proteomics-based platform can be adapted to screen for rare but treatable genetic disorders across other patient populations. Key Proteo’s patent-pending Immuno-SRM platform and associated reagent kits can perform targeted proteomic analysis of extremely low abundance peptide biomarkers from a few drops of blood. This proprietary technology expands the scope of detecting previously undetectable genetic disorders in newborns with high accuracy, effectiveness and efficiency, and has demonstrated faster turnaround times and lower costs when compared to next-generation sequencing (NGS).

FORWARD-LOOKING STATEMENTS

Certain information contained in this press release constitutes forward-looking statements. These forward-looking statements involve a number of risks and uncertainties that could cause actual future results to differ materially from those anticipated. Forward-looking statements represent the Company's estimates only as of the date such statements are made and the Company undertakes no obligation to update forward-looking statements except as required by applicable securities laws. Readers are cautioned that forward-looking statements are not guarantees of future performance and are cautioned not to place undue reliance on any forward-looking statements.

For more information, visit www.keyproteo.com.

#KeyProteo #DeNovoClassification #NewbornScreening #RareDisease #WilsonDisease #WilsonDiseaseAssociation #WiskottAldrichSyndrome #XLA #AdenosineDeaminaseDeficiency #ImmuneDeficiencyFoundation #Proteomics #Biotech #VentureCapital #LifeSciences #HealthTech #BioTechNews

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