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Verici Dx plc ("Verici Dx" or the "Company")

Successful validation of Clarava[™] from an international clinical study

Clarava™, a first-in-class pre-transplant prognostic test for risk of early kidney rejection, On track for US commercial launch by end of 2023

Verici Dx plc (AIM: VRCI), a developer of advanced clinical diagnostics for organ transplant, announces successful validation results from its prospective, blinded, international multi-centre clinical validation study for Clarava[™]. Clarava[™], is the first pre-transplant prognostic test to enable measurement of a patient's immune response to assess the risk of early kidney graft rejection. The validation study represents a significant demonstration of Clarava[™] as a predictive test capable of informing a clear, actionable response from clinicians for an estimated 65,000 eligible patients on an annual basis.

Verici Dx is on track to commence the initial US commercial launch of Clarava[™] before the end of 2023. The Company has received a preliminary Medicare gapfill median rate of \$2,650 for Clarava[™] from the Centers for Medicare & Medicaid Services ("CMS").¹

"There is a desperate global need for an effective, personalised pre-transplant test that can identify the risk of kidney transplant rejection to inform treatment decisions. The suboptimal dosing of immunosuppressants can have detrimental consequences for patients and create additional, unnecessary healthcare costs. Clarava[™] has the potential to transform kidney transplant treatment protocols and improve outcomes for patients," said Dr. Lorenzo Gallon, Medical Director of the Translational Medicine Programme, the Director of International Relations and the Director of the Renal Transplant Fellowship at Northwestern University, Chair of the Verici Dx Science Advisory Board and Non-Executive Director of the Company.

The Clarava[™] study, which included a broad and diverse group of 122 patients preparing to receive a kidney transplant and a range of rejection outcomes across 13 centres, demonstrated a statistically significant result with a sensitivity of 78% and specificity of 64%, identifying patients that are at increased risk for a kidney rejection event in the critical first 60 to 90 days post-transplant, after receiving a kidney from a deceased donor ("DD"). Study data analysis of the clinical performance of Clarava[™] demonstrated differentiation of high-risk and low-risk patient groups, determining that patients of high risk were approximately six times more likely to have a rejection than those of low risk. This represents a significant demonstration of Clarava[™] as a predictive test capable of informing for a clear, actionable response from clinicians. Whilst DDs provide the majority of kidney transplants, the Company will be also exploring further samples drawn from Living Donor (LD) transplant recipients, in addition to assessing the anticipated combination of using our pretransplant test, Clarava[™] in conjunction with our post-transplant test, Tutivia[™].

Clarava[™] is the only pre-transplant test of its kind that can risk stratify patients based on their likely immune response to a transplanted organ. This allows clinicians to identify patients most likely to require increased monitoring, including adjustments in the type, dose, and duration of immunosuppressive agents. Existing approaches to assess rejection risk are standardized and typically based on the recipient's race, age, previous transplant history and whether they have antibodies against common donor antigens. As reported, the Clarava[™] personalized risk assessment is especially important for the expanding DD transplant population.

Sara Barrington, CEO of Verici Dx, said: "This validation for Clarava is the second successful product to emerge from the Company's suite of prognostic RNA signature tests and further validates our underlying technology platform. With Tutiviä[™] commercially launched as a measure for post-transplant rejection risk, the addition of Clarava[™] as a pre-transplant test is a significant milestone in our strategy of building a complementary suite of ground-breaking products that offer end-to-end testing for kidney transplant patients and their clinicians, to help personalise care and transform outcomes."

Verici Dx is on track to commence the initial US commercial launch of Clarava™ before the end of the year to support the utility case studies and will be offered in conjunction with its other lead product, Tutivia™, which is already available in the US. The Company intends to leverage its existing internal resources and growing network of early adopters to develop the clinical positioning and marketing collateral for both products.

Notes

¹ The proposed CMS rate is currently open for public comment before it is finalised later this year. Following finalisation, the price in the Clinical Laboratory Fee Schedule ("CLFS") is valid for a period of three years from 1 January 2024, after which it is subject to further review.

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About Verici Dx plc <u>www.vericidx.com</u>

Verici Dx is a developer of a complementary suite of leading-edge tests forming a kidney transplant platform for personalised patient and organ response risk to assist clinicians in medical management for improved patient outcomes. The underlying technology is based upon artificial intelligence assisted transcriptomic analysis to provide RNA signatures focused upon the immune response and other biological pathway signals critical for transplant prognosis of risk of injury, rejection and graft failure from pre-transplant to late stage. The Company also has a mission to accelerate the pace of innovation by research using the fully characterised data from the underlying technology and collaboration with medical device, biopharmaceutical and data science partners.

The foundational research was driven by a deep understanding of cell-mediated immunity and is enabled by access to expertly curated collaborative studies in highly informative cohorts in kidney transplant.

Verici Dx's two lead products are Tutivia[™], a post-transplant test focused upon acute cellular rejection, including subclinical rejection and Clarava[™], a pre-transplant prognosis test for the risk of early acute rejection. These products seek to measure how a patient is likely to respond, and is responding, to a kidney transplant. These products are underpinned by extensive patented and published scientific research from the leading Mount Sinai Medical Center, for which the Company holds an exclusive worldwide licence.

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