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

Operational Update

First revenues from Tutivia™ following full commercial launch

Verici Dx plc (AIM: VRCI), a developer of advanced clinical diagnostics for organ transplant, provides an update on its operational progress made since the release of its interim results in September 2022.

Verici Dx continues to execute the commercial introduction of Tutivia™, the Company's first product for kidney transplant rejection, with first revenues in FY 2023 and is exploring strategic options to increase sales distribution and launch its second lead product, Clarava™ by the end of the year. The Company retains sufficient funding to achieve further key milestones in 2023 and the first half of 2024, which will support commercial adoption including the publication of additional data and obtaining both Medicare and private payor pricing and coverage.

Data continues to support product differentiation and competitive advantages
Following a robust validation trial using a varied, 'all-comers' patient population in a clinical setting, Tutivia™, a post-transplant prognostic test for the assessment of risk of acute kidney rejection, was pilot-launched in December 2022 ahead of its full commercial launch in January 2023. The validation trial data showed a positive predictive value (PPV) of 60%, over three times that was achieved by the closest comparative product in the market when used in the same context, establishing a new industry standard. Additionally, study data analysis of the clinical performance of Tutivia™ demonstrated a 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 Tutivia ^{TM} as a predictive test capable of informing a clear, actionable response from clinicians. The Directors believe that no other comparable products have been validated to this degree.

Tutivia™ also has competitive advantages, as it can be run as early as the first-week post-transplant, earlier than any other test. Tutivia™ enables clinicians to act proactively, rather than reactively, to rejection events, as well as not being confounded by other kidney health complications (such as the BK virus), which need an alternative therapy protocol. This is because Tutivia™ identifies RNA signatures that are specific to acute rejection, as opposed to other tests that detect evidence of damage that may not necessarily be caused by rejection alone.

In addition, following the positive initial data announced in September 2022 on Clarava™, the Company's pre-transplant prognostic test, the Company chose to expand its validation trial for this lead product for a further six months. This decision was taken to strengthen the publication appeal of the trial and demonstrate a statistically robust and clinically compelling case in support of the commercial rollout and adoption of the test. The full readout from this trial is expected in Q2 2023, with the initial launch expected before the end of the year.

Strong progress on rollout strategy
In line with its strategic plan, the Company is working with three leading US transplant centres in the Tutivia™ commercial launch and is supporting them with the adoption and integration of the test into the current clinical pathway, to encourage consistent and recurring utilisation. This is providing a valuable foundation for Verici Dx to make Tutivia™ as simple as possible for clinicians to use and interpret.

Following the successful progression of the Company's laboratory registration status to Compliance Certification by the Centers for Medicare & Medicaid ('CMS'), allowing its commercial operation for samples received from patients in 45 US states, Verici Dx is ready to build on the initial rollout activity over the course of 2023. Medicare and Medicaid account nationally for about 65% of all transplant patients and the Company is focused the initial rollout of the test where the proportion of Medicare patients is higher than the national average. To further drive adoption the Company has addressed the pricing and coverage determinations under Medicare. This is administered by the MolDx region of Palmetto given the Company's laboratory is based in Tennesse. The Company submitted its pricing proposal in Q1 2023 and expects to get the MolDx pricing recommendation by the end of Q2 2023. The Company is currently preparing its submission for Medicare insurance reimbursement coverage, under the Local Coverage Determination (LCD) offered in Palmetto and a coverage determination is expected later this year. Registration for Medicaid has been approved in three states and submitted in a further 11 states as well as with BlueCross Blue Shield of Tennessee, the largest health benefit plan company in the state.

Prudent cash management and execution
As of 31 December 2022, the Company had a cash balance of $9.81m. The Company has taken headcount reduction and clinical trial cost containment steps in recent months and, as a result, has extended the current cash runway to last until mid-2024. The Company is focused on early revenue generation during the first half of this year and will seek to extend and broaden its revenue streams from additional centres in the second half of 2023.

The Company expects to report its preliminary results for the year ended 31 December 2022 by the end of April 2023.

Sara Barrington, CEO of Verici Dx, said:
"We have continued to make significant progress in executing our strategy, resulting in the full commercial launch of Tutivia™ in January, with Clarava's™ initial launch expected before the end of this year.

"We achieved our internal target of attracting three key, leading US transplant sites as early adopters for Tutivia™, a critical step that is enabling us to demonstrate the adoption and integration process for clinicians.

"Looking ahead to the rest of the year, we plan to accelerate the rollout of Tutivia™ to other major transplant sites throughout the US, and to secure pricing and health insurance coverage for this lead product. For Clarava™, we expect to report validation shortly and to initiate its initial launch before the end of the year, which will support the collation of further evidence to enable a positive coverage determination. These pivotal milestones will help refine our market positioning and further accelerate

commercial uptake of both of our lead products. Verici Dx looks forward to reporting on its further progress."

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About Verici Dx plc www.vericidx.com

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 Clarava™, a pre-transplant prognosis test for the risk of early acute rejection, and Tutivia™, a post-transplant test focused upon acute cellular rejection, including sub-clinical 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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