Regulatory Story

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**Omega Diagnostics Group PLC** - ODX VISITECT® CD4 CE-Mark
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**Omega Diagnostics Group PLC**
**("Omega" or the "Company")**

**VISITECT® CD4 CE-Mark**

Omega (AIM: ODX), the medical diagnostics company focused on allergy, food intolerance and infectious disease, announces that it has CE-Marked its VISITECT® CD4 test for helping to manage people living with HIV, following successful performance evaluations in India and the UK.

The successful completion of the CE-Mark process means these tests, which indicate whether a person's CD4 count is higher or lower than 350 cells/mm³, are available for general sale through business to business channels in countries not requiring individual product registration. The technical file forms the basis of the additional regulatory approval the Company will seek through the World Health Organisation Prequalification programme which assesses *in vitro* diagnostics tests for priority diseases and their suitability for use in resource-limited settings. A successful completion of this process will enable Omega to become eligible for public sector procurement. The Company anticipates that this process is likely to be completed during the second half of the next financial year.

In addition, the Company is looking to expand its VISITECT® product portfolio and is working on an additional version of the VISITECT® CD4 test which utilises a 200 cells/ mm³ cut-off. Recent global health guidelines confirm an opportunity also exists for a test that can indicate advanced HIV disease (a CD4 cell count which is lower than 200 cells/mm³) and the Company is working to ensure it has a product portfolio encompassing both existing and new opportunities.

**Andrew Shepherd, Chief Executive Officer of Omega, commented:** "*We are pleased to have achieved this major milestone and whilst the early opportunities are likely to lead to modest sales during the next twelve months, we anticipate generating significant demand once we*

*have completed all the regulatory hurdles. We look forward to providing the global health community with unique point-of-care tests which address a significant unmet need*."

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