



6 August 2018

**Omega Diagnostics Group PLC  
("Omega" or "the Company")**

**VISITECT® CD4 Advanced Disease Development Update**  
***Key development milestone reached having attained formal design freeze***

Omega (AIM: ODX), the medical diagnostics company focused on allergy, food intolerance and infectious disease, announces the following update on its VISITECT® CD4 Advanced Disease Development programme.

The Company has achieved a key milestone by attaining the formal design freeze with its VISITECT® CD4 Advanced Disease product\*, following the successful manufacture and evaluation of three development batches. Devices from these batches were tested at two sites within Africa, on sufficient numbers of patient samples, to demonstrate that the Company now has a method for manufacturing devices which consistently meet its design specifications.

This significant development allows Omega to progress into the formal verification and validation phase. The Company will use the chosen design to manufacture three validation batches which will be sent for evaluation at selected external sites including Africa and India. These evaluation results, combined with internal verification work will, if successful, enable Omega to CE-Mark the product.

Omega remains confident in completing the verification and validation programme to deliver a unique product which will identify those people living with HIV who have advanced disease, for which there remains a significant unmet clinical need in low and middle-income countries. Once this process is completed the Company will CE-Mark the product and look to gain the appropriate regulatory approvals. We were not expecting the product to generate revenues in this current financial year and this remains the case

**Colin King, CEO of Omega commented:** *"I am delighted that we have achieved this key milestone in our development programme which further demonstrates the high level of scientific skills within the Company. This development will further enhance our product offerings for CD4 and make a significant difference to people living with HIV in resource-poor environments."*

*The information communicated in this announcement is inside information for the purposes of Article 7 of EU Regulation 596/2014.*

*\*Advanced HIV disease in adults, adolescents and children  $\geq$  five years is defined by the World Health Organisation as a CD4 cell count of  $<200$  cells/ $\mu$ L or a WHO clinical stage 3 or 4 event at presentation for care*

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