



6 March 2019

**OMEGA DIAGNOSTICS GROUP PLC**  
**("Omega" or the "Company" or the "Group")**

**VISITECT® CD4 update**

Omega (AIM: ODX), the medical diagnostics company focused on allergy, food intolerance and infectious disease, announces that it has received its first purchase orders for its VISITECT® CD4 350 cut-off test and continues to make progress with its VISITECT® CD4 Advanced Disease test.

VISITECT® CD4 350 cut-off test

The Company is pleased to report that it has received its first purchase orders for its CE-Marked VISITECT® CD4 350 cut-off test from distributors supplying into Indonesia, Moldova and Papua New Guinea. As expected by the Company, the order quantities are low at this stage and reflect distributors' intentions to seed their private business-to-business market channels in the initial stages. Nevertheless, this is an endorsement of the Company's ability to develop and then commercialise this product through the regulatory processes in international markets. We expect to supply customers before the end of the current financial year.

As previously indicated, we see Nigeria as being the single largest market for this version of the test and, whilst we are still awaiting our first order from Nigeria pending a performance evaluation, we remain confident of the potential to deliver shareholder value from this opportunity. We have received ethics approval from the National Health Research Ethics Committee of Nigeria and will provide a further update on progress of the evaluation in due course.

VISITECT® CD4 Advanced Disease test

Our VISITECT® CD4 Advanced Disease test utilises a lower cut-off of 200 CD4 cells/mm<sup>3</sup> of blood, a level at which patients' immune systems are so weakened by HIV that they are at risk of infection by other life-threatening diseases.

We have now achieved two further key milestones for this project:

- The successful completion of all internal verification studies by our development team.
- The successful completion of an external performance evaluation of venous whole blood samples.

These studies have completed in line with management's expected timelines and, to CE-Mark our Advanced Disease test, we are now only required to complete an external performance evaluation of finger prick blood samples. Progress with these evaluations is currently tracking to plan with a significant number of samples completed in Zimbabwe and India. Results to date from both sites demonstrate that the test is performing in line with design goals and we are therefore confident that we will CE-Mark this product by the end of March 2019. Achieving this critical milestone is a further step towards completing the additional regulatory processes needed to supply this product into the NGO community.

**Colin King, Chief Executive of the Group, commented:** *"We are pleased to have commercialised our VISITECT® CD4 350 cut-off test in the current financial year and I remain confident with both the near term opportunity in Nigeria and the fact that our team has shown that they can take a developed product through complex registration processes to commercialisation. In addition, the Advanced test continues to track against our timeline, which further demonstrates the significant improvements in our ability to deliver against our promises. This all bodes well for delivering meaningful revenues for CD4 in the next financial year."*

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

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