

## Regulatory Story

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**Omega Diagnostics Group PLC** - ODX VISITECT® CD4 Advanced Disease - supply agreement  
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### **OMEGA DIAGNOSTICS GROUP PLC ("Omega" or the "Company" or the "Group")**

#### **VISITECT® CD4 Advanced Disease Supply Agreement with Clinton Health Access Initiative, Inc.**

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases, food intolerance and allergy testing, announces that it has signed a supply agreement ("Agreement") with Clinton Health Access Initiative, Inc. ("CHAI")<sup>1</sup>.

The objective of the Agreement is to accelerate access to Omega's VISITECT® CD4 Advanced Disease rapid test<sup>2</sup> in low-income countries, lower-middle income countries and upper-middle income countries (together "Eligible Countries") as classified by the World Bank. The VISITECT® CD4 Advanced Disease Test is the only currently available handheld lateral flow point of care test for identifying patients with advanced HIV who are at risk of potentially life-threatening opportunistic infections.

The Agreement runs until 31 December 2021, during which time CHAI, with support from Unitaid<sup>3</sup>, will procure up to a maximum of 500,000 VISITECT® CD4 Advanced Disease tests. Within 14 days of signing the Agreement, CHAI will place an initial purchase order for 100,000 tests with delivery dependent upon demand being confirmed by certain Eligible Countries. We expect demand to be confirmed by Eligible Countries later this quarter with shipment to follow thereafter.

The supply of VISITECT® CD4 Advanced Disease tests under the Agreement will help to inform Eligible Countries with national implementation planning to support routine use of the test.

**Colin King, CEO of Omega commented:** *"We are pleased that Omega has been able to enter into this supply agreement with CHAI, who have been very supportive towards accelerating the availability of our VISITECT® CD4 Advanced Disease. This test will help support the healthcare needs of the many people in those countries that are most in need."*

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

<sup>1</sup> *The Clinton Health Access Initiative, Inc. (CHAI) is a global health organisation committed to saving lives. CHAI works with partners to strengthen the capabilities of governments and the private sector to create and sustain high-quality health systems.*

<sup>2</sup> *VISITECT® CD4 Advanced Disease is a rapid, semi-quantitative lateral flow assay for the estimation of CD4 protein on the surface of CD4+ T cells in human whole blood that indicates whether the level is above or below 200 cells/μL. It can be used in decentralised settings at the point-of-care or primary healthcare level, identifying those at risk of Opportunistic Infections and supporting diagnostic decision-making, particularly for patients living with advanced HIV disease.*

<sup>3</sup> *Unitaid is an international development agency that invests in innovations to prevent, diagnose and treat diseases including HIV/AIDS, hepatitis C, cervical cancer, tuberculosis and malaria more quickly, affordably and effectively. A growing number of Unitaid's programs address more than one disease, maximising the effectiveness of health systems.*

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