



WHO Prequalification received

OMEGA DIAGNOSTICS GROUP PLC

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

VISITECT® CD4 Advanced Disease test receives WHO Prequalification

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, announces it has received World Health Organisation ('WHO') Prequalification for VISITECT® CD4 Advanced Disease test¹. 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 VISITECT® CD4 Advanced Disease test will now be included in the WHO list of prequalified *in vitro* diagnostics ('IVD') and becomes eligible to participate in the procurement processes of UN agencies. WHO Member States are encouraged to use the WHO list of prequalified IVDs for their respective procurement decisions. The prequalification process consists of a transparent, scientifically sound assessment of products, which includes an independent performance evaluation and site visits to the manufacturer to audit the quality system and product dossiers.

This is a key commercial milestone for the Company which follows the supply agreement secured with the Clinton Health Access Initiative, Inc in April 2020, which was to accelerate access of the test to low-income countries, lower-middle income countries and upper-middle income countries (together "Eligible Countries") as classified by the World Bank.

Colin King, CEO of Omega commented: *"We are extremely pleased to receive WHO Prequalification on our VISITECT® CD4 Advanced Disease test which has allowed PEPFAR and UN agencies to get the test incorporated into their budgets for 2021 meaning the test can reach more people in those countries most in need. This has been an extensive process, and I'm proud of the team delivering on such an important milestone for the Group, in such challenging economic conditions."*

¹ 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/ μ L. 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.

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

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