



8 June 2021

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

**Regulatory progress for VISITECT® COVID-19 Antigen test**

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, provides the following update on VISITECT® COVID-19 Antigen test regulatory approvals.

**Regulatory approvals**

Omega announces that it has begun the process of engagement with its European Notified Body seeking CE marking of the VISITECT® COVID-19 Antigen test, a rapid point-of-care diagnostic test for the detection of active COVID-19 infections as a self-test. The Company is agreeing the protocols required for utilisation studies and will update shareholders as this process progresses. The test is already CE marked for professional-use and the Company is targeting approval by the end of July to allow the test to be sold in Europe for home-use as well. As the global market for Antigen testing develops the Company believes self-test approval will be a key product differentiator, as has already been seen in the UK.

The Company also announces that its technology partner, Mologic Ltd ("Mologic") has successfully completed the necessary performance studies required for regulatory approval in the US and is now in the final stages of preparing a submission to the U.S. Food and Drug Administration (FDA) requesting Emergency Use Authorization (EUA) for its rapid point-of-care COVID-19 antigen test, for use under both the Omega's VISITECT® brand and Global Access Diagnostics brand.

**Colin King, CEO of Omega, commented:**

*"I am pleased with the progress we are making to gain regulatory approval, both for our VISITECT self-test product and for US professional use. Both routes offer potentially significant opportunities as we believe we have a high quality product with global appeal."*

**Contacts:**

**Omega Diagnostics Group PLC**

Colin King, Chief Executive  
Kieron Harbinson, Group Finance Director

[www.omegadiagnostics.com](http://www.omegadiagnostics.com)

via Walbrook PR

**finnCap Ltd**

Geoff Nash/Edward Whiley (Corporate Finance)  
Alice Lane (ECM)

Tel: 020 7220 0500

**Walbrook PR Limited**

Paul McManus  
Lianne Cawthorne

Tel: 020 7933 8780 or [omega@walbrookpr.com](mailto:omega@walbrookpr.com)

Mob: 07980 541 893

Mob: 07584 391 303