



Regulatory Story

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

Ten year exclusive distribution agreement ("Agreement")

Omega, the AIM listed medical diagnostics company, announces that its subsidiary, Cambridge Nutritional Sciences Limited, (CNS) has signed a ten year exclusive distribution agreement with Toyota Tsusho America Inc., (TAI) covering the future sale and distribution of its Food Detective™ product into the US market.

Prior to being able to sell Food Detective™ in the US market, the product will first need to undergo a regulatory approval process with the US Food and Drug Administration ("US FDA"). Under the terms of the Agreement, TAI will fund the costs involved in obtaining relevant clinical data and information needed for an intended submission under the US FDA 510(k) clearance procedure which is expected to take 1-2 years.

Andrew Shepherd, CEO of Omega, said: "We're very pleased to announce this deal with TAI for distribution of Food Detective™ in the US. The product has been sold in over 50 countries and is well accepted as being a reliable test for those people suffering from the effects of food intolerance. This cost effective test has great potential in the significant US market. The US FDA regulatory approval process is likely to take time and significant resources and having a strong partner such as TAI will greatly assist this process."

Commenting on the distribution agreement, William Weiner, COO of TAI, said: "Toyota Tsusho America is excited to work with CNS by providing Food Detective™, which may help meet the needs of Americans who suffer from symptoms related to food intolerance. Food Detective™ provides TAI another proprietary diagnostic test to add to its increasing portfolio. Utilising our knowledge and experience in the diagnostic testing market in the US, along with our superior logistics, and supply chain, we look forward to selling the product through a variety of sales channels, after receiving FDA clearance."

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Information on TAI:

Toyota Tsusho America, Inc. (TAI) is a wholly owned subsidiary of Toyota Tsusho Corporation, which was founded as a trading and supply-chain specialist of the Toyota Group. TAI has been operating in North America since 1961. Over the past four decades, it has evolved from a trader in a limited number of commodities and finished goods to a multi-business enterprise.

TAI combines international trading with an expansive range of domestically targeted functions including supply-chain services and intermediate goods processing. Our operating divisions pursue a broad mix of business opportunities related to both industrial and consumer products and services.

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