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Immunodiagnostic Systems Holdings plc

US FDA 510(k) clearances for IDS-iSYS and automated Vitamin D kit

Immunodiagnostic Systems Holdings plc ("IDS"), a leading producer of diagnostic testing kits for the clinical and research markets, announces the receipt of 510(k) clearances* from the United States Food and Drug Administration (US FDA) for both the IDS-iSYS immunoassay analyser and the automated IDS-iSYS 25-Hydroxy Vitamin D immunoassay kit.

The receipt of 510(k) clearances enables IDS to market the IDS-iSYS, a fully-automated 'closed system' analyser and its flagship product, 25-Hydroxy Vitamin D, in US laboratories undertaking analyses for human diagnostic purposes. It also clears the way to market automated assays for human growth hormone (hGH) and insulin-like growth factor I (IGF-I) since these are not required to be subjected to the pre-market 510(k) process.

IDS has enjoyed sustained growth in US sales, delivering an increase in revenues of 94% to £12m (2009: £6.18m) and this follows previous growth where sales increased by 116% to £6.18m (2008: £2.86m) and more than doubling year-on-year H1 sales to £5.21m (H1 2009: £2.33m). This has been achieved with primarily 'manual' products, i.e., non-automated tests that must be performed by skilled personnel working at the laboratory bench. Much of this growth has been driven by increasing demand for vitamin D testing. The Company's manual 25-Hydroxy Vitamin D kit has enjoyed great success, with US sales having more than doubled in each of the last two years.

The majority of clinical diagnostic testing in the USA is highly automated, frequently in very large centralised 'Reference' laboratories, such as Quest Diagnostics Inc., Laboratory Corporation of America (LabCorp) and ARUP Laboratories Inc. IDS has hitherto been unable to effectively address accounts of this size and nature, but the entry of the IDS-iSYS fully-automated products into the USA will provide powerful tools to change this, and allow IDS to compete more readily with its closest competitor.

The IDS-iSYS was launched outside of the USA in February 2009 and currently offers the Bone Panel of 25-Hydroxy Vitamin D, Intact PINP, Intact PTH and N-Mid® Osteocalcin, with hGH and IGF-I within the Growth Panel. Further IDS-iSYS specific products are due to launch throughout 2010/11, including CTX-I, IGFBP-3, Bone-Specific Alkaline Phosphatase (BAP), BoneTRAP (TRACP 5b), Renin and Aldosterone. Those requiring pre-market approval will be duly submitted to the US FDA for 510(k) clearance.

Dr Roger Duggan, CEO of IDS, said:
"This is a true milestone in the history of IDS, spearheading our entry into the automated sector of the largest IVD market in the world. We have been steadily building solid foundations at IDS Inc in readiness for the launch of the IDS-iSYS and Kenneth Gibbs has created an impressive team of highly experienced professionals to handle all aspects of IDS-iSYS sales, installation, training, and technical support. The US launch comes a little later than originally anticipated, but now we can get underway with unbridled enthusiasm."

Kenneth Gibbs, CEO of IDS Inc, commented:
"IDS Inc has improved its market position during the past year with its manual vitamin D kits. Although we were delayed longer than expected in launching IDS-iSYS, we used the time effectively and beneficially to hire exceptional technical service representatives and field service engineers and fully train them to meet our customers' expectations for service and support. We are now better prepared to launch the IDS-iSYS system into the high volume testing market and we welcome the FDA clearances with great anticipation."

IDS will report results for the financial year ended 31 March 2010 on 12 July 2010.

** The US FDA requires Pre-market Notification under Section 510(k) of the Food, Drug and Cosmetic Act of an intention to market certain categories of medical device in the United States. This mandates that the IDS-iSYS instrument itself and analytes such as Vitamin D and Parathyroid Hormone (PTH) require 510(k) clearances, whilst others such as human Growth Hormone (hGH; launched in September 2009) and Insulin-Like Growth Factor I (IGF-I; launched in March 2010) have been deregulated and no longer require premarket notifications.*

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About IDS

Immunodiagnostic Systems Holdings plc is dedicated to the development and provision of innovative immunoassays for use in clinical and research laboratories worldwide. The Company is focused on creating and sustaining its position as a leading specialist in in-vitro diagnostics, building an enviable capability in de novo product design, development, manufacture and marketing.

IDS designs, manufactures and sells immunoassay kits which are used to measure or detect particular substances within a sample, thus aiding the diagnosis or monitoring of a disease or providing information for research studies. In 2007 the immunoassay sector of the IVD market was estimated to be worth US$ 10bn.