## Media Release



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## Roche Signs Exclusive Distribution Deal with DxS for K-RAS and EGFR Cancer Mutation Tests

Tests identify genetic mutations that can affect patient response to certain cancer drugs

Roche and DxS Ltd. have signed an exclusive distribution agreement for the DxS TheraScreen K-RAS Mutation Test and TheraScreen EGFR 29 Mutation Test. The tests are intended, when considered with other clinically relevant factors, to aid doctors in identifying suitable patients likely to benefit from a specific cancer therapy based on their mutation status.

"There is a growing demand for tests to indicate disease prognosis and identify patient groups more likely to benefit from a particular drug," said Daniel O'Day, President and CEO of Roche Molecular Diagnostics. "Through our partnership with DxS, we can leverage our extensive global infrastructure and commercial reach to provide these tests, which have the potential to improve treatment outcome in some patients."

Under the terms of the agreement, Roche is granted exclusive world-wide distribution rights for the K-RAS Test, which has CE Mark certification in Europe. For the EGFR test, which also has CE Mark certification, Roche is granted exclusive distribution rights for all global markets except the United States, Canada, Mexico, and Hong Kong.

"We are extremely pleased to have concluded this distribution agreement with Roche," said Dr. Stephen Little, CEO of DxS Ltd. "Not only does it enable us to meet the growing demand for these tests, but also gives doctors and patients access to standardized test results that provide further information to enhance treatment decisions."

The TheraScreen K-RAS Mutation Test was the first clinically validated, CE-Mark certified companion diagnostic for tumor-specific mutations in patients with colorectal cancer. In

addition, some drugs used to treat colorectal and other cancers are only indicated for patients who have a non-mutated (or "wild-type") K-RAS gene. The test detects seven mutations in codons 12 and 13 of the K-RAS oncogene, which are frequently found in many cancer types. These mutations are common in colorectal cancer, pancreatic cancer, lung adenocarcinoma, gall bladder cancer, bile duct cancer and thyroid cancer.

The TheraScreen EGFR 29 Test is designed to enable detection of 29 of the most common somatic mutations in the EGFR gene and detects mutations with greater sensitivity than sequencing. Recent studies in non-small cell lung cancer have shown that some patients carry somatic mutations in the epidermal growth factor receptor (EGFR) gene. These mutations may correlate with responsiveness to the EGFR tyrosine kinase inhibitors, with some mutations having a sensitizing effect and others being linked to resistance. Ongoing trials in metastatic NSCLC are investigating whether such a test could aid doctors in selecting lung cancer patients suitable for first line treatment with EGFR tyrosine kinase inhibitors, such as Tarceva, in the future.

## About DxS

DxS is a UK-based personalized medicine company providing molecular diagnostics to aid doctors and drug companies in selecting therapies for patients. DxS offers products, technology and services to the healthcare industry to enable the delivery of safe and effective medicines. Working predominantly in the field of cancer, DxS has a range of companion diagnostic and research kits that detect mutations in oncogenes associated with cancer drug response. The TheraScreen® range of CE Mark certified diagnostic products includes kits that detect mutations in the EGFR and K-RAS genes. Tumor mutation products are available for research use for EGFR, RAS, RAF, BCR-ABL and other genes that show a correlation between patient mutation status and drug response. DxS also provides a genetic analysis service to support clinical development. For more information, visit <a href="https://www.dxsdiagnostics.com">www.dxsdiagnostics.com</a>.

## **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro

diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totaled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 79,000 people. Additional information is available on the Internet at <a href="https://www.roche.com">www.roche.com</a>.

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