
Press Release

Boehringer Ingelheim and DxS sign an agreement for a companion diagnostic to identify EGFR mutations in patients with lung cancer

Manchester, UK and Ingelheim, Germany - 29 May 2009, DxS, a personalised medicine company, and Boehringer Ingelheim, a global group of pharmaceutical companies, headquartered in Germany, have entered into an agreement to provide a companion diagnostic test kit for Boehringer Ingelheim's compound BIBW 2992 (Tovok™) to identify mutations of the EGFR (epidermal growth factor receptor) in patients with non small cell lung cancer. Financial terms of the agreement are not disclosed.

Clinical data published to date suggest that BIBW 2992 offers a marked increase in efficacy in comparison to standard treatments, for lung cancer patients carrying mutations in the EGFR gene. Under the terms of the agreement, DxS and Boehringer Ingelheim will work jointly to make a suitable companion diagnostic test kit globally available.

BIBW 2992 is a novel tyrosine kinase inhibitor that acts by irreversibly blocking the EGFR /HER2 receptors, which are promoters of tumour growth. As with other tyrosine kinase inhibitor therapies, patients with mutations in the EGFR gene will be more likely to respond to a medication that targets these receptors, thereby allowing doctors to prescribe the most effective and individual treatment. Furthermore BIBW 2992 has demonstrated preclinical activity against erlotinib and gefitinib resistant mutations. With this approach, Boehringer Ingelheim is among the few companies advancing molecules of their pipeline within the area of personalised medicine.

The DxS EGFR companion diagnostic is a real-time PCR assay, designed to detect the most common mutations in the EGFR gene. The diagnostic has been developed and manufactured at DxS' head office in Manchester, UK. and will be available later in the summer for Boehringer Ingelheim's global, multi-centre Phase III clinical trial for BIBW 2992.

Commenting on this announcement, Dr Stephen Little, CEO of DxS says "This is another great endorsement of our companion diagnostic assays for predicting patient response to targeted therapies. It is an exciting step forward for personalised medicine and DxS is pleased to be at the forefront of this revolution in cancer treatment".

“As this year’s theme at ASCO highlights, it is very likely that personalised medicine will play an important role in selecting the most effective treatment for patients with cancer. We are convinced that the collaboration agreement with DxS can expedite our efforts in the field of personalised medicine. And both companies are excited to investigate how molecular diagnostics can support patient selection and help to maximise treatment outcome with our medication”, said Dr Manfred Haehl, Corporate Senior Vice President Medicine of Boehringer Ingelheim.

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About Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world’s 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 138 affiliates in 47 countries and 41,300 employees. Since it was founded in 1885, the independent, family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2008, Boehringer Ingelheim posted net sales of 11.6 billion euro while spending one fifth of net sales in its largest business segment Prescription Medicines on research and development.

For more information please visit www.boehringer-ingelheim.com

About DxS

DxS is a personalised medicine company providing molecular diagnostics to aid doctors and drug companies in selecting therapies for patients. Working in partnership with pharmaceutical companies to support the development and sales of targeted cancer therapies by providing biomarkers and companion diagnostics.

DxS has a continually expanding portfolio of cancer mutation products. The TheraScreen® range of CE-marked clinical diagnostic kits can identify genetic tumour mutations that affect how patients respond to cancer therapies, thus enabling doctors to provide the most beneficial treatment. DxS produce two clinical diagnostic kits, K-RAS and EGFR-29.

The TheraScreen: K-RAS Mutation kit is a companion diagnostic for Vectibix® (Amgen) and Erbitux® (Merck KGaA) for the treatment of colorectal cancer. DxS has an exclusive global distribution agreement with Roche Diagnostics for the distribution of the TheraScreen: K-RAS and TheraScreen: EGFR29 Mutation kits.

DxS’ pioneering real-time PCR technology Scorpions® is highly regarded for its proven speed and sensitivity, and is combined with ARMS (allele specific PCR) to develop each unique DxS product. This class-leading technology is also available for licence to diagnostic companies, for research, or for other varied applications.

DxS is a private, venture capital-backed company operating from the heart of Manchester’s Technology Quarter in the UK.

For further information please visit www.dxsdiagnostics.com.

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