

Asterand Announces New Test to Reduce Risks in Human Drug Trials

DETROIT, April 17 /PRNewswire/ -- Asterand plc announced today a new test that may be important in predicting problems before a drug is tested in live human volunteers. The company's scientists believe that the test may have been helpful in screening the drug candidate that recently caused severe reactions in a group of six young men in a clinical trial carried out at Northwick Park in London, England.

The test was developed by a team of five scientists at the US laboratories of Asterand and a summary of their work has been published recently in "Clinical Cancer Research," the journal of American Association for Cancer Research.

"This new assay is the latest of a series of experiments that Asterand can perform on human tissue samples to help drug companies test their drug candidates thoroughly so that they can put them into the clinic with increased confidence," said Asterand CEO, Randal Charlton.

The test utilizes an existing technology known as immunohistochemistry (IHC). Asterand scientists have developed a highly sensitive IHC technique for testing human or humanized antibodies being considered as drug candidates for possible side effects. The unmodified antibody under consideration is used to stain a range of human tissues -- some containing the target protein or tumor as well as normal tissue representing different parts of the body. Some of these tissues may contain the target protein and whether the target is being expressed in diseased or normal tissue can easily be determined.

"These antibodies theoretically bind to a very specific target," says Dr. Alexey Glazyrin, one of the leaders of the Asterand scientific team. "However, no one can guarantee by animal testing that the antibody does not also bind to other cells in the human body. If this happens a type 2 allergic reaction can be triggered with the immunity system launching a massive attack against the cells attached to the antibodies, as possibly happened with the drug in the recent British trial.

"Until now tests to detect the reaction to antibody drug candidates have been difficult to interpret because of the background 'noise' of other antibodies within the human body; however, the new Asterand assay is highly sensitive and we are able to obtain a clear picture of the reaction of a particular human or humanized antibody.

"So far we have used our new procedure to test over 20 antibodies under consideration as drug candidates," says Dr. Glazyrin. "We found that many of them also bound to normal tissue and the drug companies who commissioned us to do the experiments were able to review their plans before testing on live humans. We strongly suspect that a preliminary IHC test on our normal tissue array routinely performed in Asterand could have possibly predicted the unfortunate event in the recent British trial."

Dr. Glazyrin believes the new test will be increasingly valuable because of the ever-growing number of human or humanized antibodies being used as drugs which are either already on the market or in the process of development. One example of such a drug is Herceptin, used successfully for the treatment of breast cancer. Asterand demonstrated its new test detects a slightly different subset of patients that may be considered for treatment by the drug compared to the population indicated by current commercially available IHC tests.

Asterand operates laboratories in Detroit, Michigan, USA and in Royston, Hertfordshire, England. The company specializes in providing research services based on human tissue samples and data. "We help companies discover, validate, optimize and qualify drugs before they go into the clinic," says CEO Randal Charlton. "We have probably developed more experience in human tissue based research than any other

company in the world."

"We understand that animal testing plays an important role in drug development, but mice -- or in the recent case, monkeys -- are not men and the case for including research based on human tissue and data is becoming increasingly compelling. Currently we are working with 18 of the world's major drug companies on preclinical drug development."

Charlton believes that before the end of the decade, regulators will insist that trials using human tissue will be carried out in the so-called Phase 0 stage of drug development -- the period before drugs enter phase 1, 2 and 3 trials involving live humans volunteers.

"At the moment there are no firm requirements on drug companies to use human tissue research in phase 0 drug development but the US FDA is increasingly recommending its use," says Charlton.

"The unusual recent decision of the UK Medicine and Health Care Products Regulatory Agency to review their requirements in the light of the recent failed trial on the drug known as TGN142 may lead to similar recommendations or even requirements in Europe."

At the same time Charlton points out that several of the world's major drug companies are working together to review their procedures in preclinical drug development.

Notes for editors;

The technology is described in an abstract titled:

The novel, highly Sensitive Immunohistochemistry Assay for Her-2/neu Expression on breast cancer Cells using the drug Herceptin. The Journal of Clinical Cancer Research, volume 11, number 24 part 2, page 9046, poster B60, published by the American Association of Cancer Research, December 15, 2005. <http://www.aacrjournals.org>

The Asterand scientific team that developed the assay is composed of Dr. Alexey Glazyrin, Dr. Xiaoyun Shen, Nancy Lemke, Dr. Victoria Blanc and Dr. James Eliason.

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