

8th February 2006

Biofusion plc

Simcyp well placed to capitalize on House of Lords drug testing report

A report published today by the House of Lords EU Sub-Committee on Social Policy and Consumer Affairs has highlighted that 90% of medicines given to newborn babies have only been tested on adults, and that half of drugs given to children have not been tested adequately in children.

The Committee was reporting on the European Commission's proposals for paediatric medicines and their attempts to set up a common EU-wide procedure for testing and approving medicines for use in children.

This is a longstanding issue, and one which has been a focus of attention within Simcyp Limited, a Biofusion spin-out company from the University of Sheffield, which specialises in the development of software that assists the pharmaceutical industry in predicting the behaviour of drugs and new drug candidates in the body.

Traditionally drug dosages for babies and young children were simply scaled down from those in adults based on body weight or body surface area.

Dr Trevor Johnson, of Simcyp and the Sheffield Children's Hospital, has shown that this approach may result in up to 3-fold under or over dosing.

Simcyp Paediatric, a module within the Simcyp Interaction and Clearance software platform, used by most of the major global pharmaceutical companies, analyses developmental changes that affect the handling of drugs in neonates, infants and children, to assist in the establishment of safe and effective doses. By using Simcyp Paediatric, pharmaceutical companies will be able to predict doses that should result in drug exposure similar to that in adults.

Professor Geoff Tucker, the chairman of Simcyp, said:

"This is an important new development area for Simcyp and whilst the use of the software does not replace clinical studies in paediatric patients, it helps to optimise the design of such studies to ensure that the benefits of new drugs will be available to

children in a safer and faster manner. In this way, it will facilitate the implementation of new legislation, established in the USA in 2002 and soon to be introduced in Europe, in ensuring that new medicines will be tested adequately in children."

David Baynes, CEO of Biofusion, said:

"Simcyp continues to lead the way in developing software applications for predicting drug clearance interactions for the major pharmaceutical companies and with the new EU law due to be introduced in 2007 Simcyp is again well placed to capitalise on this developing sector of the market."

Contacts

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About Biofusion

Biofusion was established in 2002 to commercialise university-generated IP. The Company has agreed a ten-year exclusive arrangement with the University of Sheffield for the commercialisation of IP owned by the University in the area of medical life sciences. The agreement also gives Biofusion shareholdings in an existing portfolio of eight spin out companies including Axordia, Celltran and Simcyp. The University of Sheffield is a world class life sciences research centre, spending £30m in 2002/3 on research in medical life sciences. This spending level is expected to grow year on year giving an estimated £0.5bn of research funding over the next ten years. The University, which celebrates its centenary this year, can count five Nobel Prize winners among its alumni and researchers, and data from the latest UK Government's Research Assessment Exercise 2001 ("RAE 2001") showed it ranked fifth in the UK for the quality of its life sciences research.

About Simcyp

Simcyp Limited is a spin-out company from the University of Sheffield, UK, that develops software and databases specifically designed to inform the processes of drug discovery and development by simulating virtual patient populations to identify individuals at extreme risk. The Company is supported and guided by a Consortium of global pharmaceutical companies and the US FDA.

In 2004, Prof Geoff Tucker (Professor of Clinical Pharmacology and Head of the Academic Unit of Clinical Pharmacology at the University of Sheffield, and Chairman of

Simcyp Limited) and Dr Amin Rostami (Reader in Pharmacokinetics at the University, and Director of Research and Development at Simcyp Limited) were jointly awarded the New Safer Medicines Faster Award 2004 by the European Federation for Pharmaceutical Sciences (EUFEPS). This award recognises their pioneering work in predicting population variability in whole body pharmacokinetics and drug-drug interactions.