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Simcyp enhances flagship Simulator in line with pharmaceutical industry priorities

Sheffield, UK. 6th May 2009... Simcyp Limited, the leader in the simulation and prediction of clinical drug-drug interactions, has expanded the capabilities of its world-class Population-based ADME Simulator.

Version 9.0, released today, was developed in consultation with the Simcyp Consortium of global pharmaceutical companies including Pfizer, AstraZeneca and Johnson & Johnson. The Consortium's top priority was the implementation of a model accommodating the effects of influx and efflux transporters which are increasingly becoming a focus for regulatory agencies including the US FDA.

The transporter feature further advances the Simcyp Simulator's ability to reflect 'real-life' population variability in the processes of drug absorption, distribution, metabolism and excretion (ADME) through the conduct of studies in virtual human populations.

Drug development researchers using Simcyp Version 9.0 now have the capability of modelling the absorption of drugs which are inhaled or applied to the skin. In addition, enhancements to trial design elements within the Simulator provide greater flexibility to assess the potential outcomes of Phase I, II or III clinical trials early in the drug development process. Examining complex and potentially dangerous scenarios and assessing the likelihood of such cases in the safety of a computer allows clinical studies to be optimised, prioritised or even abandoned.

Professor Amin Rostami-Hodjegan, Director of Scientific Research and Development at Simcyp, commented: *"The realisation that there is virtually no end to the number of various studies which would be required to cover all possible permutations of clinical scenarios and patient populations in real life, has encouraged implementation of more modelling and simulation strategies into drug development. The new version of the Simcyp Simulator takes us, once again, another step towards the optimal use of routinely generated in vitro data and the integration of relevant prior knowledge to inform drug development processes"*.

Dr Steve Toon, Executive Director at Simcyp, commented: *"The Simcyp Consortium model has been very successful for many years as it has allowed us to provide the most relevant and up-to-date tools to streamline drug development and help satisfy regulatory requirements. The ability to adapt quickly to industry needs, which has been the hallmark of Simcyp, is essential as Pharma increasingly adopts modelling and simulation as a strategic tool in early drug development."*

The Simcyp Consortium, which meets annually to discuss industry issues and determine the future direction of Simcyp's cutting-edge R&D, has already voted on priority features to be incorporated into Version 10 of the Simcyp Simulator.

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About Simcyp

Simcyp provides a platform for modelling and simulation of drug absorption, distribution, metabolism and excretion (ADME) in virtual human populations. The Simcyp Simulator, used by nine of the top

ten pharmaceutical companies worldwide, is recognised as the industry's most sophisticated platform for the simulation of drug-drug interactions and pharmacokinetic outcomes in clinical populations.

Simcyp also runs interactive workshops on the optimal use and interpretation of *in vitro* ADME data; offers consultancy services on a range of ADME and pharmacokinetics/pharmacodynamics (PK-PD) issues and supports academic research through the provision of not-for-profit licenses.

For further information please visit www.simcyp.com

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