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InnoMed PredTox Consortium Presents Final Results From Non-clinical Safety Studies

On October 13, 2008 the InnoMed PredTox Consortium, a joint Industry and European Commission collaboration to improve drug safety, will meet in Basel to present conclusions from a 36-month non-clinical safety study. The consortium has been assessing the value of combining results from molecular profiling technologies with results from more conventional toxicology methods for more informed decision making early in the non-clinical safety evaluation of new drug candidates.

The project addresses the problem that about 90% of all compounds entering non-clinical development currently fail to reach patients despite huge efforts from the pharmaceutical industry and billions of euros of spending, according to the European Federation of Pharmaceutical Industries and Associations (EFPIA).

As part of the project the partners collected and analysed 1.3 terabytes (1300 MB) of transcriptomics, proteomics, metabolomics and conventional toxicological data, including histopathology and serum chemistry, on 14 failed drug candidates together with two reference compounds, troglitazone and gentamicin. The compounds originally had been developed for their potential to treat significant diseases such as diabetes and central nervous system disorders but then had to be excluded for therapeutic use due to serious adverse effects in liver and kidney tissues. In order to integrate experimental data across different technology platforms, as well as to enable joint analysis at different sites, all project-related information is stored in a relational database custom-developed by Genedata, one of the technology partners.

During the meeting in Basel, hosted by F. Hoffmann-La Roche and Novartis, researchers from 12 pharmaceutical companies, three Universities and two technology providers will gather to agree on the concluding project report and recommendations on the future practice of drug safety assessment. Preliminary statements from senior project members indicate that while traditional toxicological approaches, especially histopathology, will not be replaced within the next few years, recent molecular profiling technologies will gradually move to the centre stage. The reason for this lies in the benefits of understanding the mechanistic foundations of adverse effects and the high level of measurement specificity.

One of the meeting hosts, Dr. Thomas Singer, Global Head of Non Clinical Safety at F. Hoffmann-La Roche Ltd., summarized industry expectations, saying, "InnoMed PredTox is a unique experience of intimate collaboration between leading pharmaceutical companies and partners from academia and small to mid-size enterprises (SMEs). The encouraging results from this project have motivated the industry to expand this type of collaboration in the new framework of the joint Innovative Medicines Initiative of EFPIA and the European Commission. We expect that this work eventually will have a significant impact on the drug development process and regulatory decision making."

About InnoMed PredTox

InnoMed PredTox aims at reducing a key bottleneck in the R&D process namely the assessment of drug safety before new drugs enter the market. It has secured €8 million over 40 months and is partly funded by the European Commission Life Sciences, Genomics and Biotechnology for Health Priority (LSHB-CT-2005-518170). The project is coordinated by the European Federation of Pharmaceutical Industries and Associations (EFPIA), a body representing the research-based pharmaceutical industry and biotech SMEs operating in Europe. The members in the consortium include: Bayer Schering Pharma, Boehringer

Ingelheim, F. Hoffmann-La Roche, Johnson & Johnson Pharmaceutical R & D, Lilly S.A., Merck KGaA, MerckSerono, Nycomed, Novo Nordisk A/S, DK, Novartis, Organon, Sanofi-Aventis (Germany, France), Servier, the Universities of Dublin, Hacettepe and Würzburg, as well as Bio-Rad and Genedata. For more information, please visit www.innomed-predtox.com.

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