



## **Top Institute Pharma**

### **International Scientific Review Committee**

Report on the fourth meeting, October 17 and 18, 2007 in Leiden, the Netherlands

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## **Report of the fourth meeting of the International Scientific Review Committee (ISRC) on October 17 and 18, 2007, in Leiden**

### **Summary**

The ISRC convened for the fourth time on October 17 and 18, 2007, in Leiden to discuss (scientific) progress in setting up TI Pharma as well as the strategic plan. The committee is pleased with the progress made since the April meeting. Next to starting up the individual projects, a considerable effort was devoted to set up and run the Education & Training program. The committee is enthusiastic about the plans for sustainability of TI Pharma and is favorably impressed by the work done on Most Neglected Diseases. TI Pharma is well ahead of the EU Innovative Medicines Initiative but should make sure its name and concept are known within the EU.

## **Introduction & agenda**

On Wednesday October 17 and Thursday October 18 the ISRC convened for the fourth time with the TI Pharma Management Team and program staff.

Members of the ISRC are:

Prof. dr. E.J. Ruitenbergh (chair, Professor of International Public Health, Free University Amsterdam, ex RIVM and Sanquin)

Prof. dr. A.T. Florence (former Dean of the London School of Pharmacy)

Prof. dr. P. Krosgard Larsen (President of the Carlsberg Foundation and professor at the Danish University of Pharmaceutical Sciences)

Dr. R. Laing (WHO Geneva, author of the Priority Medicines report)

Prof. dr. L. Lesko (Food and Drug Administration, USA, unable to attend the fourth meeting)

Prof. dr. R. Metternich (Merck Research, West-point, Pennsylvania, USA, unable to attend the fourth meeting)

Prof. dr. T.M. Jones, CBE (ex Wellcome Foundation, ex ABPI)

The meeting, which started on Wednesday afternoon and lasted until Thursday afternoon, focused on:

- A status update regarding starting up the TI Pharma Strategic Research Program, and the Education & Training program
- A discussion with Principal Investigators and project managers of three projects
- A presentation and short discussion on the TI Pharma strategic plan
- An extensive discussion on work done in the area of Most Neglected Diseases
- A detailed overview of the Education & Training program and the European ambitions within this area

Each of these topics is addressed below.

## **Status update**

The committee was updated on the status of the implementation of the Strategic Research Program. At the time of the meeting 21 Project Agreements were signed and 7 were in the signing round. The other 16 Project Agreements should be signed before the deadline, which was endorsed by the committee, of December 31, 2007. If indeed all projects will commence, the expectation is that no budget will be available for a third call within the framework of the current government subsidy.

It is good to see that already some 40% of all available positions have been filled. The committee shares the priority setting of the directorate and program staff to promote recruiting.

The week after the ISRC meeting the first Drug Development Simulation course starts showing that the Education & Training program is up and running. The Netherlands is clearly leading in Europe with respect to Education & Training in the biopharmaceutical sciences, a fact which is also shown by the inventory of courses made by TI Pharma. TI Pharma now has to work on its European ambitions.

The annual report which has been published looks very professional. The content is strong and it is good to see that the start of the Institute has been properly documented. The committee made some constructive suggestions to improve next year's annual report.

### **Discussion with PI's and project managers**

Three projects were presented by the Principal Investigators and Project Managers, and discussed in detail:

T3-112: TNF Ligands in cancer – PI: Steven de Jong

T4-102: Malaria – PI: Robert Sauerwein and project manager Monika Alon

T5-107: Endocannabinoid – PI: Jeffrey Glennon

These discussions were lively and generated critical questions to sharpen the projects further. The ISRC concludes, also in line with the projects discussed at the previous meeting that the projects are run by high quality investigators and project managers.

### **Strategic plan**

The committee is pleased to see the ambitious plans for sustainability of TI Pharma and endorses the directions chosen to further build the Institute. The committee made several suggestions for improvement.

### **Most Neglected Diseases**

The committee is favorably impressed by the analysis on Most Neglected Diseases. The initial focus on two technology platforms (Fixed Dose Combinations and Hot Medicines) and two therapeutic indications (Helminths and Leptospirosis) is good. Especially the therapeutic areas are truly neglected. All four are areas in which the Netherlands can take up the role as coordinator, building upon top expertise available.

Two other therapeutic areas (Dengue and Leishmaniasis) certainly need more efforts but this should be done in close collaboration with the Novartis Institute for Tropical Diseases in Singapore (for Dengue) and the Drugs for Neglected Diseases initiative (DNDi) in Switzerland (for Leishmaniasis).

As soon as preliminary results are available in the technology platforms, the Gates foundation should be contacted. These technology platforms can provide an important input to its work on the big three (Malaria, HIV/Aids and Tuberculosis).

The efforts to raise funding for these topics, which are now starting, should include the Ministry of Foreign Affairs (Development Cooperation) next to the Ministry of Health.

### **Education & Training and European ambitions**

The Drug Discovery and Drug Development Simulations have great potential to run them in other places, outside the Netherlands. However, it should be noted that first further experience will have to be gained with running the course for TI Pharma fellows. The committee advised to find some form of market-protection for the course concept and content. The inventory of available courses is impressive. It demonstrates great potential to roll it out on an European scale within the context of the EUFEPS Training Platform. TI Pharma, and the Netherlands in general, should keep on telling Europe about the quality of the Dutch Education & Training infrastructure. It is leading in Europe and this should be made known.

To help individual fellows in their training needs, various competence profiles could be developed. Providing these profiles to fellows and their supervisors can assist them in choosing the courses to fulfill their needs.

A limited number of master classes should be started, for example on success and failures of drug introductions. In such master classes expert views can be exchanged from academia, industry, regulatory bodies and the government.

In conclusion, the committee is pleased to see that TI Pharma stays on track to make a difference, both in the Netherlands as well as on an international scale.