



# 2nd European Summer School on Clinical Pharmacology September 11-15

2003



**Budapest** 

**Hungary** 

#### Dear Colleague,

it is my pleasure to announce the 2nd European Summer School on Clinical Pharmacology jointly organized by the European Association for Clinical Pharmacology and Therapeutics (EACPT) and the Hungarian Society for Experimental and Clinical Pharmacology (MFT).

The success of the 1st European Summer School on Clinical Pharmacology held in Antalya, Turkey in 2001 motivated the EACPT to introduce a curriculum of Summer Schools to be hold every year and located in different countries.

The aim of the Summer School is to improve the knowledge and skills of young colleagues interested in clinical pharmacology. The School gathers the attendants from the host country and her region primarily. Distinguished lecturers are invited from Europe and the host country. The lectures cover broad aspects of clinical pharmacology.

Hungary is a traditional meeting point for scientists in Europe. People are friendly, the landscape is beautiful and the climate in September is usually mild. Budapest, the capital of Hungary has 2 million inhabitants. The city is called the "Pearl of Danube" by many visitors.

I encourage you to join the Summer School 2003 in Budapest!

Prof. Adam Vas, MD, PhD Secretary 2nd European Summer School on Clinical Pharmacology Delegate to the Council of EACPT

### **European Summer School on Clinical Pharmacology 2003**

#### organized by

# EACPT and the Hungarian Society for Experimental and Clinical Pharmacology

#### 1. Date

September 11-15, 2003 (Thursday to Monday)

#### 2. Venue

Hotel Tulip Inn Budapest Millenium H-1089, Üllői út 94/98 Budapest, Hungary

#### 3. Registration fee:

680 EUR

#### 4. Participants

Young (preferably bellow the age of 35 ys) interested persons coming primarily from

- Bosnia Hercegovina Bulgaria Croatia Czech Republic
- Estonia Greece Hungary Latvia Lituania Poland
- Romania Serbia Montenegro Slovakia Slovenia Turkey
- Ukraine

#### 5. Under the auspices of

Prof. Dr. Sylvester E. Vizi, President of the Hungarian Academy of Sciences

#### 6. Organizing Committee

- Prof. Dr. János Borvendég
- · Prof. Dr. Csaba Farsang
- Prof. Dr. Béla Gachályi
- Prof. Dr. Sándor Kerpel-Fronius
- Dr. Péter Kovács

- Prof. Dr. Kornélia Tekes
- Prof. Dr. Ádám Vas (Secretary)

#### 7. Financial Committee

- Dr. Péter Kovács
- Prof. Dr. Ádám Vas

#### 8. Scientific Advisory Board

- · Prof. Dr. János Borvendég
- · Prof. Dr. Csaba Farsang
- · Prof. Dr. Béla Gachályi
- Prof. Dr. Zsuzsanna Fürst
- Dr. Péter Kovács
- Prof. Dr. Tamás Paál
- Prof. Dr. Gyula Papp
- Prof. Dr. Kornélia Tekes

#### 9. International Advisory Board

- Prof. Dr. Michael Orme
- Prof. Dr. Folke Sjöqvist
- Prof. Dr. Cankat Tulanay
- Prof. Dr. Giampaolo Velo
- Prof. Dr. Vitan Vlahov

#### **Programme**

#### Thursday, September 11th

9.00-20.00 17.00 Registration

**Opening Session** 

Greetings

( Prof. Gyula Telegdy, President of the Section of Medical Sciences, Hungarian Academy of Sciences )

What is pharmacology?

( Prof. János Szolcsányi, Head,

Department of Pharmacology, University Pécs )

Clinical pharmacology in Europe: an example of successful international diversification

( Prof. emeritus Folke Sjögvist, Chairman of the Clinical

Division of IUPHAR, Huddinge, Sweden)

• The Hungarian pharmaceutical industry

( Dr. László Buzás, Director of the Hungarian Pharmaceutical

Manufacturers Association )

20.00 Welcome dinner

#### Friday, September 12th

8.00-8.45	Pharmaceutical research and development process ( Prof. Jochen Kuhlmann, Bayer AG., Germany )
8.45-9.30	Pharmacogenomics
	( Prof. Jeffrey R. Idle, Univ. Bern, Switzerland )
9.30-10.15	Pharmacokinetics: Basic concepts
	( Dr. László Vereczkey, Chemical Research Centre,
	Hungarian Academy of Sciences )
10.15-10.30	Coffee break
10.30-11.15	Drug Interactions
	( Prof. Kálmán Magyar, Semmelweis University Budapest )
11.15-12.00	Pharmacovigilance
	( Prof. Gianpaolo Velo, University of Verona, Italy )
12.00-12.45	Pharmacoepidemiology
	( Dr. Ulf Bergman, Huddinge Hospital, Sweden )
12.45-13.45	Lunch
14.15-17.00	Visit to the Clinical Pharmacology Lab. of the Semmelweis
	University Dept. Forensic Medicine. Introduction into methods.
	( Dr. Kálmán Róna, Head )
19.30	Dinner at the venue

#### Saturday, September 13th

8.00-8.45	Clinical trials: human phase I II, bioequivalance
0.45.0.00	( Prof. Béla Gachályi, MÁV Hospital, Budapest )
8.45-9.30	Clinical trials: human phase III-IV
	( Dr. Judit Kapocsi, Szt. Imre Hospital, Budapest )
9.30-10.15	"Significant" questions of clinical pharmacology
	( Dr. László Tótfalusi, Semmelweis University Budapest )
10.15-10.30	Coffee break
10.30-11.15	Responsibilities of the sponsor
	( Prof. Ádám Vas, Gedeon Richter Ltd., Budapest )
11.15-12.00	Responsibilities of the investigator
	( Dr. Péter Kovács, Debrecen University of Sciences )
12.00-12.45	Endpoints and surrogate markers is clinical trials
	( Prof. Vitan Vlahov, University Hospital "Queen Giovanna",
	Sofia, Bulgaria)
12.45-13.45	Lunch

14.15-16.00	Visit to the Phase I Unit of the MÁV Hospital in Budapest: Practical aspects of conducting clinical trials ( Prof. Béla Gachályi, MÁV Hospital, Budapest )
17.00	
	Guided tour in the City
20.00	Dinner at the venue

## Sunday, September 14th

9.00-9.45	Drug regulations in the EU ( Prof. Gunnar Alvan, Medicinal Products Agency, Uppsala, Sweden )
9.45-10.30	Drug regulations in Hungary ( Prof. Tamás Paál, National Institute of Pharmacy, Budapest )
10.30-11.15	ICH GCP
	( Prof. János Borvendég, National Institute of Pharmacy, Budapest )
11.15-11.30	Coffee break
11.30-12.15	Tripartite ICH: are we bystanders or participants?  ( Prof. Milan Stanulovic, University of Novi Sad, Yugoslavia )
12.15-13.00	Ethical considerations in clinical trials
	( Prof. Tamás Fenyvesi, Semmelweis University, Budapest )
13.00-13. 45	The role of CROs
	( Dr. János Antal, Parexel Hungary, Budapest )
14.00-15.00	Lunch
18.00	Gala dinner on a Danube steamship with the evening panorama of Budapest

# Monday, September 15th

8.30-9.15	Pharmacoeconomics
	( Prof. Lajos Matos, MedRepked Kft., Budapest )
9.15-10.00	Education on clinical pharmacology : EU
	( Prof. Theo deVries, Free University of Amsterdam,
	Netherlands
10.00-10.45	Education on clinical pharmacology: Hungary
	( Prof. Sándor Kerpel-Fronius, Semmelweis University
	Budapest)
10.45-11.00	Coffee break
11.00-12.00	Test
12.15	Issue of certificates
12.30	Closing remarks and farewell
	( Prof. Ádám Vas, Gedeon Richter Ltd., Budapest )