



HEPATITIS C

*Some important facts on the alarming situation in
Central and Eastern Europe*



According to the World Health Organization (WHO), about 170 million people (roughly 3% of the world's population) are infected with Hepatitis C and are at a clear risk of further developing liver cirrhosis and liver cancer. Each year, the number of newly infected patients with the Hepatitis C virus (HCV) lingers from between 3 and 4 million. The HCV is a major cause for acute hepatitis and chronic liver disease, including cirrhosis and liver cancer.

The chronic viral hepatitis C is a potentially life-threatening disease for which there the current therapies are in a very early stage of investigation and optimization, and which has a strong tendency to chronicity, and ultimately, to hepatocellular carcinoma.

In Eastern Europe, the figures are alarming, with almost 9 million people infected with HCV. Our collaborator Professor Dr Zahary Krastev, the main and most respected infectiologist and gastroenterologist in **Bulgaria** has stated it very clearly: *"The number of Hepatitis C virus (HCV) carriers is very significant: chronic carriers of the anti-HCV antibodies constitute about 1.5% of the population. It is estimated that about 1% of the country's population suffers from Hepatitis C related chronic liver diseases. A surge in the number of intravenous drug users forms the basis of a new range of patients with chronic Hepatitis C, about 65% of which are anti-HCV positive, the majority with HCV type 1."*

But this is not an isolated case in Eastern Europe. In the **Russian Federation** for example, official figures confirm over 1.2 million patients suffering from acute and chronic hepatitis C. Most of these patients cannot receive an antiviral therapy because the health authorities of Russia are not in the position to finance the medicaments for the whole course of the therapy.

The worldwide established standard treatment against the HCV, consisting of antiviral drugs such as interferon, (wheter alone or in combination with ribavirin), has proven to be differently effective. While interferon alone has shown to be effective in 10-20% of the cases, the combination of interferon with ribavirin rises to a range between 30-50%. Unfortunately, as in the case with HIV, the antiviral treatment of chronic Hepatitis C is tremendously expensive, and therefore not available to most of the patients infected with the virus.

In the whole **Eastern European** area, there is an alarming increase in the number of new infections of the Hepatitis C Virus, among other reasons, for the contagion through blood, and mostly due to the widespread sexual contacts without protection of any kind. A lot of young adults are affected, and because the therapy is of such an expense, there is a large number of naïve patients, who hope to get this treatment in the framework of a clinical trial.

We at "S&P" Pharmatest Management are aware of the intensive worldwide efforts in clinical investigation to fight against hepatitis C. Therefore, a large network of specialized hepatothologists and gastroenterologists are working with us in their clinics and centres with an impressive number of naïve untreated patients that are keen to participate in clinical studies in order to receive a correct treatment, which otherwise they would not be able to pay themselves. The recruitment speed of these centres is correct and almost 5 to 7 times faster than in comparable specialized centres throughout Western Europe or the USA, with time savings up to one year per study as the rule.

In all of our specialized centres, the liver biopsy, specific hepatitis diagnosis and histological examination (e.g. metavir score) are standard procedures, and therefore available for your clinical studies surrounding hepatitis C or any other hepatological issue. We are working with the main specialists in each country, opinion-leaders themselves who ensure a highly qualified performance of the study, according to the international standards of ICH-GCP. S&P has also long experience in the use of large commercial laboratories as unified central laboratories for a unified control of the course of the study.

We are taking the liberty of sending you a brief questionnaire on the next page which we ask you to fax back if interested.

Yours truly,

Dr. Alexander Siebel
Medical & Managing Director

www.pharmatest.net



Your opinion is important for us. We would like to know what you think of us and our reports, so please take a few minutes to fill up this short questionnaire and fax it back to us (+49 30 6937500). By helping us, we become better for you.

1. Do you have R&D experience in Central and Eastern Europe?

- Not at all, Poor, Reliable, Good, Excellent

If yes, in which countries? And on which indications?

2. For which indication would you like to receive more detailed information on Central and Eastern Europe?

- Hepatitis C, Oncology, Diabetes, Gastroenterology, Urology, CNS (e.g. Alzheimer), HIV/AIDS, Cardiology, Ophthalmology, Gynaecology, Other

3. For the study approval process in which of these countries would you like to receive further information?

- Bulgaria, Croatia, Czech Rep., Hungary, Mexico, Latvia, Lithuania, Poland, Romania, Guatemala, Russia, Slovakia, Ukraine, Argentina, Other

4. What R&D fields are most important for you to be covered in Central and Eastern Europe?

Table with 5 columns: Field, Very important, Important, Also significant, Secondary. Rows include Phase I-IV, Local-based project management, Study approval services, etc.

5. What are the qualities you value the most for your choice of Central and Eastern Europe?

Table with 5 columns: Quality, Very important, Important, Also significant, Secondary. Rows include High recruitment rates, Significant savings in timeline, ICH-GCP compliance, etc.

Name: _____

Company: _____

Department / Position: _____

Phone: _____

Fax: _____

E-mail: _____