

## Invitation to the ELPA symposium

# „Compassionate Use in Hepatitis C: Saving lives of patients who cannot wait“

### Time:

Saturday,  
27th April 2013  
11.15 – 13.15



### Venue:

EASL Congress 2013  
RAI Convention Centre  
Hall 20  
Europaplein  
Amsterdam

### Programme:

#### Opening

Prof. Thomas Berg, professor of Medicine University Hospital Leipzig, Germany

#### EASL view on HCV compassionate use programmes

Daniele Prati, EASL Governing Board, Director of the Department of Transfusion Medicine and Hematology at the Ospedale Alessandro Manzoni, Lecco, Italy

#### HCV compassionate use programmes for people living with HIV/HCV co-infection

Luis Mendao, EATG

#### HCV compassionate use programmes from a European regulatory perspective

Filip Josephson, EMA

#### HCV compassionate use programmes: The French experience

Daniel Dhumeaux, Professor of Hepatology at the University of Paris-Est, Chair of the French Masterplan for prevention, screening, and management of viral hepatitis, France

#### HCV compassionate use programmes in Italy

Massimo Puoti, Chief of the Infectious Diseases Department of the Ospedale Niguarda Cà Granda, Milano, Italy

#### Bulgarian National Hepatitis Plan and compassionate use regulations

Dessislava Dimitrova, Deputy Minister of Health, Bulgaria

#### A living example

Ivan Gardini President EpaC, Italy

#### Recommendations for new guidelines

Prof. Thomas Berg, professor of Medicine University Hospital Leipzig, Germany

#### Panel Discussion

**The symposium is open to the general public.**

**A registration to the EASL congress will be necessary to enter the building.**

# Introduction

I would like to cordially invite you to our ELPA symposium: **“Compassionate Use in Hepatitis C: Saving lives of patients who cannot wait”**. The event will take place during the annual EASL congress in Amsterdam on 27th April 2013.

In spite of the medical progress, many hepatitis C patients still cannot benefit from currently approved therapies. A large proportion of these patients already suffer from advanced liver disease and comorbidities such as HIV coinfection, renal or heart disease. They are at the highest risk of dying within the next years if their hepatitis C infection is not cleared very soon.



Promising new treatments are being explored in trials, which may be better tolerated and have shown to achieve between 85–100 % cure rates in selected patient groups. However, patients with advanced liver disease are usually excluded from clinical trials. Even approved medicines with good results are not authorised for seriously ill patients until several years later, or not at all. The situation of these patients may be compared with “starving to death in front of a candy shop window”: They die while they are hearing about potentially life-saving new medicines, which will not be made available for them in time.

**Compassionate use** programmes for HCV patients with advanced disease are urgently needed. “Compassionate use” means that a promising new medicine is made available to patients with life-threatening, long-lasting or seriously disabling illnesses: This is possible even when a medicine has not yet been authorized for their condition, and entering a trial is not an option. Specific regulations and precautions need to be observed, as there may be unknown safety risks and open questions about the optimal dosage and treatment duration. As a consequence, even compassionate use programmes have exclusion criteria which mean that many seriously ill patients cannot participate in them.

Both the European Liver Patients Association (ELPA) and the European Aids Treatment Group (EATG) are currently exploring this subject together with experts and stakeholders. What are the chances and pitfalls of compassionate use in hepatitis C? How can it best be implemented to save lives, while protecting patients from complications, and doctors against legal difficulties? At our ELPA symposium, hepatologists, representatives from the European Medical Agency, the Bulgarian Deputy Minister of Health and patient advocates will share their views, experience and expertise and on compassionate use.

**Tatjana Reic, President**  
**European Liver Patients Association (ELPA)**

## Confirmation

Please mail your confirmation to Deutsche Leberhilfe in Cologne, Germany. Alternatively, you can fax them at +49-221-2829981 or email them at [info@leberhilfe.org](mailto:info@leberhilfe.org)

Deutsche Leberhilfe e. V.  
„ELPA Symposium 2013“  
Krieler Str. 100  
D-50935 Cologne  
Germany

- Yes, I would like to attend the ELPA symposium on 27th April 2013
- No, I cannot attend.
- Please send me the press materials.

Title: \_\_\_\_\_  
Name: \_\_\_\_\_  
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