European Medicines Agency
Press office

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Press release
'First-in-man' clinical trials guideline released for public consultation

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a draft guideline on requirements for first-in-man clinical trials for potential high-risk medicinal products. The draft guideline is being released for a two-month public-consultation period.

Following extensive review and discussion of the very serious adverse reactions that occurred during the first-in-man clinical trials of TGN1412, national competent authorities in the EU Member States, together with the EMEA and the European Commission, decided to produce this Community guideline as one of the measures for minimising the risk of such serious adverse reactions occurring.

The guideline has been prepared by experts in clinical trials and non-clinical research from the national competent authorities and CHMP working parties. It builds on principles laid down in European legislation and existing guidelines.

The focus of this new draft guideline is on potential high-risk medicinal products, i.e. products where the mode of action, the nature of the target in the human body or the limited relevance of animal models for the prediction of pharmacological or toxicological effects in humans raises concerns that serious adverse reactions may occur.

The draft guideline gives guidance on managing the transition from non-clinical studies, e.g. studies in animals or *in vitro* studies, to first tests in humans for the abovementioned type of products. It covers quality, non-clinical and clinical aspects, including the calculation for the first doses to be given to human subjects, the initial dose-escalation trials and the management of risk.

Following the conclusion of the two-month consultation period, a meeting will be held at the EMEA with key stakeholders (European Commission, national competent authorities, pharmaceutical industry, patients' and healthcare professionals' organisations, academia and learned societies) to consider the feedback received and to finalise the guideline for publication thereafter.

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NOTES:

1. The aim of the first-in-man clinical trials guideline is to provide a common approach across EU Member States to the design and conduct of first-in-man clinical trials of potential high-risk medicinal products. The draft guideline can be found here. Comments are invited by 23 May 2007, and should be submitted using the template available here to paivi.vuoti-karvonen@emea.europa.eu
2. A Community guideline is a document considered to provide advice to sponsors, applicants or marketing authorisation holders, national competent authorities and/or other interested parties on the best way to fulfil an obligation laid down in the Community pharmaceutical legislation. Scientific guidelines are Community guidelines that relate to specific scientific issues and reflect a harmonised EU approach, based on the most up-to-date scientific knowledge. Guidelines are not binding. Sponsors may deviate from the recommendations of the guideline provided they can substantiate their approach.
3. Clinical trials are undertaken to allow data on the safety and efficacy of new medicinal products to be collected. The first-in-man trial is the initial step of the clinical development of a medicine in humans and is part of the Phase-I or early-development clinical trials. Phase-I trials are designed to look at the initial safety and tolerability, as well as the pharmacology and pharmacokinetics

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

of the medicinal product concerned. Studies in this phase of development usually have non-therapeutic objectives and may be conducted in healthy volunteer subjects.

4. Clinical trials are regulated by European Union Directive 2001/20/EC, of 4 April 2001. The Directive harmonises across EU Member States the administrative provisions governing clinical trials, as well as the standards of good clinical practice (GCP) and good manufacturing practice (GMP) to which they are conducted. It is the responsibility of national competent authorities to assess applications to conduct clinical trials with medicinal products.
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to
Martin Harvey Allchurch and Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail: press@emea.europa.eu