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Objet : [MEMBERS] European activists require regulatory agencies

European activists require regulatory agencies to halt unethical trial

Pfizer recruiting for phase II dose-finding trial for investigational compound offering no safety net: “The trial design should be changed or otherwise stopped”, declares Mauro Guarinieri, Chairperson of the EATG.

Brussels, 11 April, 2005

“Pfizer’s trial is not ethical for people living with HIV”, strongly warns Nikos Dedes, Greece, Chairperson of the European Community Advisory Board (ECAB), the treatment working group of the European AIDS Treatment Group (EATG). “The trial design should be changed or otherwise stopped”, declares Mauro Guarinieri, Chairperson of the EATG. “We demand all concerned regulatory authorities to assume their responsibility and act accordingly,” adds Mr Guarinieri.

What causes these two well-known activists to make such strong statements is the fact that Pfizer, the world biggest pharmaceutical company, is implementing a trial for its investigational HIV drug whose design, according to activists, is unnecessarily putting people with HIV and with severe immune suppression at risk.

To summarise the situation, the A26 trial is a PhaseIIb/III study to define the dose, preliminary efficacy and safety of the CCR5 chemokine inhibitor known as UK -427,857, or maraviroc, in participants who have never taken treatment before. The inclusion criteria allow individuals to enter the trial regardless of their CD4 count and viral load. This includes people with CD4 counts below 200 and viral loads over 100,000 copies. According to this trial design, patients who are in vital need for a potent and well-proven antiretroviral treatment regimen will therefore be included in a dose-finding trial of an investigational compound.

Results from several well-known cohort studies have shown that such patients are more likely to develop an opportunistic infection and eventually progress to AIDS, and are therefore in vital need of a potent and well-proven antiretroviral treatment regimen. All existing treatment guidelines are in line with this recommendation. In addition to this, newly diagnosed patients with advanced disease are generally not in the best position to make an informed decision on participating in a clinical trial or not.

David Haerry, Switzerland, ECAB Co-Chair, says that “there is currently little clinical data available (about 10-day monotherapy in a few dozen patients) for the anti-CCR5 compound being developed by Pfizer. It is totally unacceptable to treat naïve patients with severe immune suppression and high viral loads with a drug combination containing an investigational drug whose potency and ideal dose are still unknown”. Haerry stresses that a failure in this patient population, either due to potency or adverse events, has an important impact on both the physical and psychological well-being of the patient and may impair future treatment options.

Mr Dedes nevertheless clarifies that, “the development of new ARV drug classes is essential to treat experienced patients in need of effective salvage regimens. But in the case of naïve patients, new drug classes are less urgent given the number of effective treatment options available.” In the light of these considerations, the EATG has objected to the proposed phase II trial designs for the CCR5 inhibitors. Three companies are currently enrolling patients for this compound in phase II trials.

The phase II design for the Pfizer compound was discussed at a meeting between the leading European researchers, the EATG and National Community Advisory Board representatives in November 2004 in Glasgow where, according to the European activists, “Pfizer committed to adapt the trial to those recommendations at a global level,” says Mr Haerry.

The initial trial design was then challenged at a national level by several national community advisory boards and regulatory authorities. Other requirements imposed by the latter caused Pfizer to withdraw the trial from some of these countries (France and Germany) or to stop it (Spain). Pfizer still announced that they would proceed in recruiting for the initial trial design without offering the safety restrictions as they were recommended by the group who met in Glasgow.

Despite all these objections, recruitment for the trial is taking place in Belgium, Italy, Switzerland, and the United Kingdom.

The EATG denounces Pfizer’s move as irresponsible and ethically questionable.

Pressure and requests for the fast development of investigational compounds in the name of patients with no options or other competitive considerations cannot justify putting naïve patients’ health at unnecessary risk.

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About the EATG. Founded in 1991 as a co-operative structure of people from

different nationalities and communities affected by HIV in Europe the EATG is a non-profit organisation registered under German law, with its secretariat in Brussels, Belgium. Since its establishment the EATG has been at the forefront of the development of the civil society response to the HIV/AIDS epidemic in Europe. The EATG has members from 29 different European countries, , who are involved in 58 local NGOs and related to 36 community networks. The mission of the EATG is to enable people with HIV or at risk of HIV infection and their advocates to provide significant input into the process of developing, testing and approving HIV treatments; to advocate for best practices of care and treatment for all persons living with HIV/AIDS; to advocate for the rapid introduction of existing and new HIV treatments; to promote the availability of appropriate information about HIV treatments for people with HIV, their health care providers, and health policy makers; to advocate for changes in legislation and patent law as well as for the medical evaluation of generic medicines; and to advocate for changes in legislation and policies affecting the health, rights and quality of life of people with HIV. In reaching its objectives the EATG has committed itself to be democratic, accountable, transparent and accessible to people living with HIV and their advocates, taking into account diversity of gender, religion, culture and beliefs. The EATG is funded with both public grants and private donations.