TRT-5 PRESS RELEASE

HIV Infection: Discontinuation of a Clinical Trial in France, Germany, and Spain

First antiretroviral, first European outcry for Pfizer

The leading global pharmaceutical company but a novice in HIV treatment, Pfizer prefers to not undertake a trial to evaluate a new antiretroviral in France, Spain, and Germany, rather than conform to the principles of protection of individuals participating in research, as defended by the associations and health agencies.

The Pfizer laboratory is about to finally announce that it will not undertake trial 1026 in France, Spain, and Germany. This trial was to evaluate the optimal dosage of a new medication against HIV/AIDS (an anti-CCR5) in hundreds of HIV-infected patients not yet having taken antiretrovirals.
In competition with Schering and GSK who in turn are developing their own anti-CCR5, Pfizer, despite its inexperience with HIV treatment, chose to avoid losing time with the ethical concerns of associations and health agencies.

What was the focus of these concerns? The Pfizer trial planned to expose patients with extremely weakened immune defenses, having a known high risk of death, to a treatment including an experimental product whose efficacy and tolerance have not been evaluated for longer than 10 days.
However, these patients must instead receive a "treatment of optimal and validated efficacy" (1) which is today possible due to the antiretrovirals on the market in France. **In the absence of preliminary data in patients in less advance immunoviral stages, this trial exposes the very immuno-suppressed patients to an unnecessary risk and is contrary to the international recommendations regarding research ethics (2).**

Based on this report, TRT-5 (3) demanded Afssaps to examine the Pfizer trial protocol. Without waiting for either the position of Afssaps or the opinion of the CNS (1), Pfizer recently

TRT-5

TRT-5 [GROUPE INTERASSOCIATIF TRAITEMENT & RECHERCHE THERAPEUTIQUE]
TOUR ESSOR. 14_ RUE SCANDICCI_ 93508 PANTIN CEDEX FRANCE_ www.trt-5.org

COORDINATION DU TRT-5 :
ELISE BOURGEOIS-FISSON T. 01 41 83 46 11_ F. 01 41 83 46 19_ E-MAIL : bourgeois-fisson@trt-5.org
CORINNE TAÉRON T. 01 44 93 29 21 _ F. 01 44 93 29 30 _ E_MAIL : taeron@trt-5.org

ACTIONS TRAITEMENTS_ T. 01 43 67 66 00 : MAREK KORZEK, EUGENE RAYESS, FRANK RODENBOURG
ACT UP_ T. 01 49 29 44 75 : †NATHALIE DAGRON, GUY MOLINIER, FABRICE PILORGE, HUGUES FISCHER, OLIVIER HEINIS
AIDES_ T. 01 41 83 46 46 : DOMINIQUE BLANC, BRUNO SPIRE, FABRICE MÉTAYER, FRANCK BARBIER
ARCAT_ T. 01 44 93 29 29 : †MICHELE AILLOT, MIGUEL-ANGE GARZO, CORINNE TAERON, MARIANNE L'HÉNAFF, MIGUEL DE MELO
DESSINE MOI UN MOUTON_ T. 01 40 28 01 01 : GEORGES POINT
NOVA DONA_ T. 01 43 95 81 75 : CHRISTIAN HUCHET
SIDA INFO SERVICE_ T. 01 44 93 16 44 : MAXIME JOURNIAC
SOL EN SI_ T. 01 48 31 13 50 : FRANCOISE THURET

announced that it is withdrawing its trial in France. It did the same in Spain and Germany, where agencies similarly voiced criticism regarding trial 1026.

Despite the multiple attempts at negotiation with associations of European countries and with the EATG (European Aids Treatment Group), Pfizer chose defiance: it withdrew from countries where health agencies acted in support of the concerns of the associations, and did not at all change its trial in countries where patients are alone against laboratories. It plans to perform its drug trials in countries where the regulations are less constraining, ethics are more flexible, and access to care is more difficult than in France. Thus the conclusion to be drawn: the competitiveness of Pfizer research is based in large part on the social instability of patients enrolled in its studies. TRT-5 is concerned about what is to become of these patients, particularly those with more advance cases of HIV.

Pfizer declares that it has set itself on an "ambitious challenge": "to meet the demands of the AMM (4) for 20 new drugs, or new treatment guidelines, by the end of 2006" (5). To put medications on the market as fast as possible, at the expense of the ethics of their development (and their concern for the patients), is the credo of Pfizer. Is this really what we expect from the pharmaceutical industry? TRT-5 fights against this purely financial logic, which puts in peril the patients participating in the research.

TRT-5 continues to reaffirm its commitment in favor of clinical research which respects the patients and their needs. **If it remains crucial to develop new therapies for people infected with HIV/Aids (and particularly for patients in whom the virus is resistant to existing treatments), TRT-5 refuses that the research is done to the detriment of the persons participating in the research.**

Press Contacts: Hugues Fischer +33 6 15 01 61 73 / Elise Bourgeois-Fisson +33 6 88 26 66 05

(1) "Avis sur les conditions de participation à des protocoles d'essai clinique de nouveaux traitements, pour les patients infectés par le VIH et n'ayant jamais pris d'antirétroviraux," (Advice concerning the conditions of participation in clinical trial protocols for new treatments, for patients infected with HIV and who have not taken an antiretroviral.) Conseil national du Sida, March 17, 2005.
(2) The ethical principles on biomedical research established by the World Medical Association stipulating how the interest of patients participating in research takes precedence over the interests of science. (Helsinki Declaration).
(3) TRT-5 (Traitements et Recherche Thérapeutique) assembles the associations Aides, Act Up-Paris, Actions Traitements, Arcat, Sida Info Service, Sol En Si, Dessine Moi un Mouton et Nova Dona.
(4) Authorization to put on the market.
(5) "Pfizer, premier investisseur mondial privé en recherche biomédicale" (Pfizer, first private global investor in biomedical research), Pharmaceutiques, November 2004.