TRT-5 PRESS RELEASE

# The safety of clinical trial participants takes precedence over the private interests of pharmaceutical companies.

**TRT-5 (1) welcomes the opinion of the National Council on AIDS (Conseil National du Sida or CNS), which has reasserted that patients'interests must override scientific and social interests.**

**Can persons who are infected with HIV, and have just learned they are HIV positive and deeply immunosuppressive, but have never been on antiretroviral therapy, be put at risk by an experimental treatment for which the optimal dosage is not even known, whose efficacy and tolerance, combined with other ARVs, has not been assessed over a period of more than ten days, and only in a few patients? Is this possible in a context where tested combinations, the optimal efficacy of which has been confirmed, are available?**
By putting forward an opinion on March 17, 2005 (2) in plenary session, the National Council on AIDS has unequivocally answered the questions raised by the TRT-5 group.

(…) "promotors should first, in the early stages during which optimal doses are determined, ascertain that the new treatment, when combined with other antiretroviral medication, is both effective and well-tolerated in patients whose illness is little-advanced, e.g. with CD4 levels exceeding 200/mm$^3$ and viral load below 100 000 copies/ml. Regarding the need to also obtain data regarding treatment-naïve patients at a later stage of illness, CNS feels that they can be included in the assessment of the new treatment, **but only later in the process, once safety and efficacy have been confirmed for lower-risk patients**."

This is a sensible opinion based on much convergent medical data, which is true to the facts : « Patients never having taken antiretroviral medication, with severe immune depression (CD4<200/mm$^3$) or AIDS, show **a higher risk of morbidity and mortality** in the three years following the start of care. This is why **it is vital that they receive, as early as possible in the care cycle, treatment that offers optimal and confirmed efficacy**."

The CNS opinion thus puts an end to a dispute which has been going on since the end of 2004, a period during which three big pharmaceutical companies announced their plans to develop new ARVs, CCRS inhibiters (the co-recepter CCRS enables the HIV to attach itself to the T CD4 lymphocite). It was clear these companies were more concerned with enrolling patients quickly, than with ensuring their long-term or medium-term safety. Besides, these CCRS inhibiters are the first of a totally new therapeutic category whose positive and negative impact is still largely unknown.

Contacts : Corinne Taeron +33144932921 / Elise Bourgeois-Fisson +33141834611

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

TRT-5 PRESS RELEASE

The French Agency concerned with the safety of health products (Agence française de sécurité sanitaire des produits de santé or Afssaps), which has taken up the issue under the pressure of associations, can now use a well documented opinion to require more safety for clinical trial participants from pharmaceutical companies.
Must it be repeated that French legislation also requires that "*the interests of biomedical research participants must always override the sole interests of science and society*"?
It is probable that responsible companies will comply with such a rule and implement the CNS recommendation.

(1) TRT-5 (Treatments and Therapeutic Research) is a coalition of the following associations : Aides, Act Up-Paris, Actions Traitements, Arcat, Sida Info Service, Scl En Si, Dessine-moi un mouton and Nova Dona.

(2) " Opinion on Participation in Clinical Trial Protocols On New Treatments for HIV-Infected Patients Never Having Taken Antiretroviral Medication ", Conseil National du Sida, March 17, 2005

Contacts : Corinne Taeron +33144932921 / Elise Bourgeois-Fisson +33141834611

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