

Paris, October 31 2007

ANRS and the ORANGE FARM 2 STUDY: ANRS 12126

Dear Colleagues,

As head of the French National HIV/AIDS and Viral Hepatitis Research Agency (ANRS), I am writing to you about the ORANGE FARM 2 study and relations between ANRS – the sponsor –, the investigators, and NGOs in France and South Africa.

I would like to clarify the position of ANRS, in order to ensure that ORANGE FARM 2 moves forward in the best possible conditions.

1. ANRS funding for this study represents a significant proportion of the Agency's resources. ANRS is not the only funding source, but it is the trial sponsor, which entails a certain number of responsibilities.

This study is part of the North-South/South-North partnership, concerning studies conducted in the southern hemisphere with a Northern Investigator, and Southern Investigator, and many other important partners in both hemispheres.

2. In recent months we have had a series of meetings between the chief investigator, ANRS representatives (including myself), and French HIV/AIDS NGOs, which raised a number of concerns regarding the conduct of the study. The French NGOs consider this to be an important study, and wish to see it move forward, but they raised a number of issues, in writing, that were discussed at the different meetings.

One concern is the social science studies that could be part of ORANGE FARM 2. A meeting of French researchers, French NGOs and two South African researchers took place at ANRS in late September 2007 on the subject of *Human and social issues relating to circumcision studies, and particularly ORANGE FARM 2*. Some points are not yet settled.

3. Last September, after these meetings, French NGOs made two requests:

- To receive more information on ORANGE FARM 2 than that contained in the documents that they has so far received,

- The need for a “community consultation process” conducted by the local community and Ngos.

I agreed to this notion of community involvement, provided the consultations would not take too long and did not take up too many resources. The French NGOs said they did not wish to conduct the community survey themselves, but wished to draw up a joint project with South African NGOs, that would then be discussed with French NGOs and with ANRS. We agreed that this process could begin in October, but the precise modalities of the survey remained to be decided. It was agreed that it would be up to South African NGOs to decide exactly how to involve the community. However, it seems clear to me that this community consultation should include all those involved in the study and all concerned South African NGOs, including TAC.

I understand that several projects have been proposed by South African NGOs. The best project, and one that is compatible with the time frame of the study, must now be chosen. The study investigators must be informed as soon as possible of the precise conditions in which this community consultation will take place, and must also be asked for their input, so that the chosen project meets with universal approval, from ANRS, the study investigators, and local South African NGOs.

4. To obtain a first-hand view of the situation, I will visit South Africa during the week of 12 November 2007, accompanied by Brigitte Bazin, head of ANRS Research for the southern hemisphere. I am intending to meet local researchers and also patient associations, including TAC.

The following timetable seems realistic:

- ANRS visit to South Africa in mid-November
- Discussions with French NGOs and the chief investigators in late November on proposed community surveys, and to exchange information.
- The funding of the community survey needs to be decided.
- The community survey could start in late December or early January 2008, with results available in late January 2008
- The slow phase of ORANGE FARM 2, with a limited time scale and study population, could start in mid-December 2007 at Orange Farm, so that the researchers can assess, based on the first enrolments, the difficulties they are likely to encounter.
- The results of the community survey and the slow study (fewer than 100 participants) can be examined together in February 2008, together with their implications for the conduct of the ORANGE FARM 2 study.

5. May I ask you all solemnly, not only as head of ANRS but also as a physician who has been working in the field of HIV/AIDS for many years, both with researchers and with NGOs, to carefully consider your positions, and the way you state them, in the coming weeks.

Prevention is entering a tricky phase. The results of the MERCK adenovirus trial, which will start to be published on 8 November 2007, are even worse than expected. You are also aware of the disappointing results of the

microbicide trials presented this summer in Sydney. This means that, among all the promising new preventive measures discussed at the Toronto conference in August 2007, only two are left: circumcision and preps.

The international community is therefore supportive of this type of study -- but not at any price – and the onus is now on us to arrive at an acceptable compromise.

It is perfectly normal for each player to hold a clear-cut position, but this should not mean trying to force it on the other participants, to the detriment of this important research. I am sure we all agree on the need for ANRS to conduct such a study in the very near future.

If we keep in mind the overriding goal of our work – the future well-being of Africans at risk of HIV/AIDS -- then I am sure that we will be able to overcome the difficulties we are currently facing.

I will try to meet with as many South African NGOs as possible during my visit in 15 days' time.

Amicalement,



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