

To : Franz Humer
Roche CEO
F. Hoffmann-La Roche Ltd
Group Headquarters
Grenzacherstrasse 124
CH-4070 Basel - Switzerland

Paris, September 4th, 2007

Dear Mr Humer,

The product Fuzeon® (enfuvirtide) has demonstrated its efficacy in controlling the viral replication in HIV patients confronted with severe therapeutic failure.

For quite a high number of patients, Fuzeon® is still a necessary component of the antiretroviral treatment to keep a viral load below the level of detection.

Unfortunately, patients taking Fuzeon® often face considerable drawbacks. Of course, there is the constraint of the two injections per day. But the injection-site reactions (ISR) of Fuzeon® are even harder to endure, and they heavily undermine the quality of life of HIV patients. With two daily injections, even if the patients strictly respect the precautions for use, they can rapidly be covered with nodules.

We have seen the first results obtained with Fuzeon® and the medical device Biojector 2000® in a Canadian clinical trial : we do know that Biojector 2000® is not an ideal solution, that this device has also some drawbacks (for instance, transient neuropathy), but we consider that it can improve pain and adherence to treatment in some patients who suffer a lot from the local side effects of Fuzeon® standard needles.

We have also been informed that the results of two clinical trials, run in the United States with Fuzeon® and Biojector 2000®, are about to be released (1). If these results confirm that Biojector 2000® improves pain and adherence in a majority of patients, we have been told that Roche will submit a file to the Food and Drug Administration (FDA) in order to include in the labelling of Fuzeon® the possibility to use Biojector 2000®.

However, up to now, Biojector 2000® is not available in France and in Europe.

In France, we think that around 1000 patients are currently taking Fuzeon®. The well-known ISR of Fuzeon® are discouraging for a lot of patients, and they are also the reason why doctors sometimes don't propose Fuzeon® to patients in need.

TRT 5

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Among patients taking Fuzeon®, many have only one idea in mind : to stop this drug as soon as possible. These early treatment discontinuations cause prejudice to patients whose viral load can rapidly grow without an adapted combination of efficacious antiretrovirals.

For instance, a clinical trial (TRIO, promoted by the French National Research Agency on AIDS and Viral Hepatitis - ANRS) which evaluates an innovating combination of antiretrovirals (raltegravir + darunavir + etravirine + optimized background treatment - OBT) in heavily pretreated patients is currently ongoing in France. Fuzeon® is recommended as a component of OBT in order to reach and maintain undetectability. Just a few weeks after the beginning of the trial, some patients are already thinking to stop Fuzeon®, whatever their virological results and outcome are. They are already fed up with the nodules induced by Fuzeon®.

Thus, Fuzeon® side effects clearly compromise the patients outcome. And for that, it is absolutely necessary to find a solution to improve Fuzeon® tolerance.

Moreover, we want to underline that, as time goes by and as the problem of ISR persists with no perspective of solution, the image of Fuzeon®, and by the same way the image of Roche in HIV, is deteriorating.

We would like to know your plans about Biojector 2000® and its availability / accessibility for French and European patients in need. More precisely, if the results of the two clinical trials run in United States are conclusive, we ask Roche to set up a compassionate trial with Biojector 2000® as soon as possible in France. This trial could allow to gather some new and useful datas on Biojector 2000®. But this trial could also allow French patients to have an accelerated access to Biojector 2000® and maybe could avoid some premature treatment discontinuations. This trial could do the link with the availability of Biojector 2000® in the context of its marketing in France and Europe.

We do know that, as Biojector 2000® has an EC labelling since March 2007, setting up such a compassionate clinical trial is totally feasible in France.

By organizing such a compassionate access to Biojector 2000®, Roche could demonstrate that it strongly cares about patients health and quality of life. We thank you in advance for the consideration you will have for French patients taking Fuzeon® and this request of accelerated access to Biojector 2000®. We don't doubt that Roche's researchers are strongly involved to find a better formulation of Fuzeon®.

Of course, we are looking forward to your answer, and we would appreciate to meet Roche representatives to discuss this issue in details.

Yours sincerely,

Corinne Taéron, for TRT-5

Copy to :

- Jean Marimbert, Executive Director, French Medicines Agency (Afssaps)
- Roselyne Bachelot-Narquin, French Ministry of Health
- Eric Abadie, Chairman of the Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMA)

(1) « Roche and Trimeris Provide Update on Development of Needle-Free Administration for FUZEON® » · <http://www.rocheusa.com/newsroom/current/2006/pr2006101101.html>