April 5, 2006

Miles White
Chairman and CEO
Abbott Laboratories
100 Abbott Park Road
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Dear Mr. White,

We are writing to you to express our concern about the lack of availability in developing countries of the new melt extrusion (Meltrex) formulation of lopinavir/ritonavir (LPV/r), marketed as Kaletra (200/50mg tablets).

LPV/r has been recognized as an essential medicine by the WHO[1] and will be included in its revised antiretroviral treatment guidelines[2], in which boosted protease inhibitors represent the cornerstone of second-line therapy. As you know, the tablet formulation of LPV/r, approved by the US Food and Drug Administration in October 2005, has critically important advantages for patients in developing countries: no dietary restrictions, lower pill burden, and most importantly, storage without refrigeration. Due to the storage requirements of the old formulation, there is the risk that some patients in tropical climates are currently using degraded LPV/r capsules. In short, there is an urgent need in developing countries for access to the new heat-stable formulation of LPV/r, as no other boosted protease inhibitors are practical to use in the hot climates of many of these countries.

We urge Abbott to take the following actions to make this crucial second-line option accessible in developing countries:

1. **Immediately file for registration of the new LPV/r formulation in all countries where the old formulation was registered or pending, as well as in other developing countries.**

According to the WHO/AMDS registration database[3] published in October 2005, the old formulation of LPV/r (133/33.3 mg soft gel capsules) is registered in 55 countries and registration is pending in 13 others, covering 68 of the 69 countries eligible in Abbott's Access Program.[4] But the new formulation of the drug has not been registered in any country except for the US. We urge you to immediately file for registration of the new formulation of LPV/r (200/50mg tablets) in developing countries, so that the old formulation can be replaced by the new one, as was done in the US.

2. **Communicate the countries and the filing dates where registration of the new formulation of LPV/r is pending and a timeline for submissions to remaining countries.**

We ask that Abbott communicate the countries and the filing dates where registration of the new formulation of LPV/r is pending so that health advocates in these countries can work with national drug regulatory authorities to overcome any delays and provide a timeline for submitting remaining registration requests.

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[1] 14th edition, WHO Model List of Essential Medicines (revised March 2005)
[2] Complete guidelines for adults and adolescents are forthcoming. A preliminary summary is available for consultation at http://www.who.int/3by5/mediacentre/news51/en/
[3] http://ftp.who.int/htm/AMDS/drugsdatabase.pdf (LPV/r is not listed as registered or pending in Eritrea which is eligible for Abbott's Access Program)
[4] http://www.accesstohivcare.org/en/partners/countries.aspx

3. Publish a price for the new formulation of LPV/r for least-developed and middle-income countries.

Since May 2002, Abbott has been selling the old formulation of LPV/r in Africa and Least Developed Countries for $500 per patient per year on an FOB basis (freight, insurance, customs handling, taxes and duties paid by purchaser). Abbott has not yet made public any price for the new formulation of LPV/r in developing countries. We ask that Abbott establish a price that is at least as low as the price for the old formulation in least-developed countries.

Abbott's Access Program for the old formulation of LPV/r excludes middle-income countries, resulting in prices up to 12 times more than in least-developed African countries.[5] We urge you to make the new formulation available at an affordable price in middle-income countries where millions live on less than US $2 per day.

4. Develop a heat-stable formulation of RTV and make it accessible in developing countries.

A separate, heat-stable formulation of ritonavir (RTV), marketed as Norvir, is also needed in developing countries so that care-providers can implement the forthcoming WHO guidelines and pair RTV with other available and affordable, heat-stable protease-inhibitors.

5. Develop a pediatric formulation of the new formulation of LPV/r.

WHO draft pediatric guidelines recommend LPV/r for use in children if there is cold-chain access.[6] While this new formulation overcomes the storage challenges presented by the old formulation, care-providers would not be able to cut or crush tablets because the new LPV/r is a coated tablet. Therefore, care-providers need a pediatric version of this formulation so that they can provide adequate second-line regimens for children as well as adults.

6. Work with countries to make the new formulation of LPV/r easily available while registration applications are being considered.

Because the drug registration process can take months if not years to complete, we ask that Abbott establish a reliable interim system to distribute this new formulation to treatment programs in developing countries while registration is pending.

Sincerely,

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[5] Doctors Without Borders/Médecins Sans Frontières Briefing Note, "Abbott's New and Improved Kaletra: Only in the US," February 2006
[6] http://www.who.int/hiv/pub/guidelines/PaedARTguideDRAFT_webreviewNOV05%20_2_.pdf

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