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Open Response to Abbott Laboratories' Letter to MSF on March 17, 2006

March 23, 2006

Miles White
Chairman and CEO
Abbott Laboratories
200 Abbott Park Rd.
Abbott Park, IL 60064-6189

Sent via facsimile and email

Dear Mr. White,

We received a letter from Ms. Heather Mason of Abbott Laboratories dated March 17, 2006. On behalf of Doctors Without Borders/Médecins Sans Frontières (MSF), I would like to respond to a number of the issues raised in this letter and request a clear response regarding whether or not Abbott will fulfill MSF's order (purchase order number 31556) of 4,762 bottles of heat-stable lopinavir/ritonavir at the cost of no more than \$500 per patient per year placed on March 15, 2006.

Abbott writes that patients in the countries for which we have ordered the new version of lopinavir/ritonavir (LPV/r) have ready access to the old, soft-gel version. To suggest that this is an adequate interim solution until Abbott makes the new heat-stable tablet formulation available in developing countries ignores the practical constraints that form the basis for MSF's order. The refrigeration requirement for the old lopinavir/ritonavir formulation makes it virtually impossible to use in many of MSF's projects. Furthermore, in middle-income countries, such as Thailand and Guatemala, the price Abbott charges for the old version makes it inaccessible to both the government and individual patients. At present, the new heat-stable lopinavir/ritonavir is the only field-adapted, boosted protease-inhibitor, and so MSF continues to urge Abbott to take action to accelerate access to this formulation in developing countries.

MSF is concerned that Abbott is introducing additional obstacles by making any discussion of the fulfillment of MSF's order contingent on proof of MSF's acquisition of special authorizations in each country. Some countries, such as Kenya and Uganda, request an order confirmation indicating batch number, price, date of delivery, and origin of shipment to obtain this authorization. Abbott's delay in providing this information prevents MSF from taking the necessary steps to request special authorizations. MSF has extensive experience acquiring the necessary authorizations whenever we import unregistered medicines.

MSF has requested that our order be delivered to MSF's procurement center (MSF Logistique), a bonded pharmaceutical warehouse in France so that the process of fulfilling the order and securing special authorizations can occur simultaneously, to avoid unnecessary delays. While we have no objection to sharing special authorization documentation with you, there are no legal or regulatory requirements that

prevent Abbott from shipping heat-stable lopinavir/ritonavir to MSF's warehouse. Other companies regularly ship medicines to MSF Logistique.

In your letter, Abbott states its intention "to achieve rapid regulatory approval to benefit patients." However, Abbott has not indicated a policy change to immediately begin filing for registration in developing countries. Abbott has publicly stated that it needs a Certificate of Pharmaceutical Product (CPP) from the European Union in order to register the drug in African countries because the new version of lopinavir/ritonavir is manufactured in a plant in Germany. Yet, a CPP is not required in all developing countries, and for the regulatory authorities that do require a CPP, this document could be generated by the US FDA if Abbott chose to export from the US. Therefore, there is no barrier to filing for registration in developing countries, and MSF again urges Abbott to immediately begin filing for registration.

MSF was encouraged to receive confirmation from Abbott Laboratories on March 13 that it is developing a heat-stable formulation of ritonavir. Access to heat-stable ritonavir will give care providers options other than new lopinavir/ritonavir. As per the forthcoming WHO guidelines, they can pair this with other available and affordable, heat-stable protease-inhibitors produced by other pharmaceutical companies. MSF would like to know the target date for availability of this new formulation.

MSF calls on Abbott to take the necessary steps to fulfill MSF's order and make heat-stable lopinavir/ritonavir available and affordable in developing countries as numerous HIV/AIDS researchers, care-providers and treatment advocates urged in a letter to you dated March 15, 2006. As always, I am available to meet with you personally, and I look forward to your prompt response.

Sincerely,



Nicolas de Torrente
Executive Director

cc:

Heather Mason, Vice President, International Marketing, Abbott Laboratories
Robert Dintruff, Director, Global Cares Initiative, Abbott Laboratories
Rita Roy, Global Citizen Shop, Abbott Laboratories