Date: May 25, 2010

To: Principal Investigators and Study Coordinators Participating in P1071, Phase I/II Open Label Pharmacokinetic Safety, Tolerability and Antiviral Activity of Vicriviroc, A Novel CCR5 Antagonist in Combination Regimens in Antiretroviral Therapy Experienced Children and Adolescents

From: The P1071 Protocol Team

Subject: Clarification Memo #1 for P1071, Version 2.0, dated 6/5/09 - Change in vicriviroc storage temperature and shipping address

1) The storage temperature for vicriviroc study products as described in the last sentence in the second paragraph in Section 5.2 is changed to read: Both vicriviroc maleate table formulation and oral solution should be stored up to 25°C (77°F); do not freeze or refrigerate.

2) Vicriviroc and ritonavir plasma samples for pharmacokinetic analysis will be collected throughout the study. Due to a change in site responsibilities, sample testing will be performed at the Summit, NJ facility. The complete mailing address for sample shipment is:

Merck
Attn: Debra Post
181 Passaic Ave / S7 Receiving
S7, E1
Summit NJ 07901

This Clarification Memo can be obtained from the P1071 Protocol Specific Webpage of the IMPAACT Website (http://www.impaactgroup.org/P1071-protocol-specific-web-page). The username is: impaact and the password is: cure (all lower case). The document is available under ‘Current Protocol Related Documents’.

Please contact the protocol team at actg.teamp1071@fstrf.org if you have any questions.

Thank you for your interest and participation in P1071.