

## **ADDENDUM CONSENT/AUTHORIZATION FOR PARTICIPATION IN THE CLINCARD PROGRAM**

**TITLE OF STUDY:** A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subjects

**PROTOCOL NO.:** PN021 Extension Study

### **Introduction:**

The sponsor of the study is making available to you a Clincard Reimbursement Card, an SMS (Short Messaging Service and/or text message service) and email service that will allow you to receive reimbursement for regular site visits as well as certain reminder text messages on your cell phone and/or emails. You may consider the following information to help you decide if you would like to use any of these optional services.

It may add to or change the information in the consent form you signed at the start of this study. You will receive a signed and dated copy of this consent form addendum for your records.

### **Purpose:**

As a participant in the MK-1439A Protocol 021 study extension, you will be paid 50 dollars per visit to help cover the cost of travel and expenses.

- Week 100
- Week 116
- Week 132
- Week 148
- Week 164
- Week 180
- Week 192

You will be paid for each visit that you complete, even if you do not complete the overall study. If you have a pre-existing agreement for payment of expenses incurred during your participation in this study extension, please consult the study staff for more information.

Additionally, you will have the option to receive updates related to payment reminders via text message and/or email message (standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages.

**Do I have to use any or all of this service?**

You do not have to use any part of the service. Your decision to use this service is entirely voluntary. If you decide to use the service, you may decide at any time that you no longer want to use the service and may cancel it by contacting the study site and the site will withdraw you from this service. If you decide not to use the service, or you decide to cancel the service, you can still take part in the clinical study.

**What am I being asked to do?**

Greenphire will act as an agent of the SPONSOR to manage the reimbursement and text messaging/email process. You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto following completion of monthly study visits. When a study visit is completed, funds will be approved and loaded onto your card. The funds will be available within 1 week and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, you can contact Greenphire support at (866) 952-3795. Your doctor can discuss alternate methods of payment if you decide you do not want to participate in the ClinCard program.

**What do the messages say and what do I have to do?**

The messages will not identify you individually or include any reference to the medication you are taking. If you decide to opt-in for the text messaging and email reminders, you may receive:

- 1 payment notification after each visit
- 1 balance reminder after 5 ½ months of no activity

The text messages and/or emails will say the following:

**Payment Confirmation (SMS & Email)**

Schedule	Upon funds being loaded onto the ClinCard
Message Structure	Hi [FIRST NAME], \$[PAYMENT VALUE] has just been loaded onto your ClinCard and is available immediately.
Message Example	Hi Sam, \$50.00 has just been loaded onto your ClinCard and is available immediately.
Subj. Line (Email)	ClinCard Deposit Notification

**Balance Reminder (SMS & Email)**

Schedule	After 5 ½ months of no activity
Message Structure	Hi [FIRST NAME], \$[CURRENT BALANCE] is currently available

	on your Clincard for use. Please visit <a href="http://myclincard.com">myclincard.com</a> or call 1-866-952-3795 to manage your account.
Message Example	Hi Sam, \$37.26 is currently available on your ClinCard for use. Please visit <a href="http://myclincard.com">myclincard.com</a> or call 1-866-952-3795 to manage your account.
Subj. Line (Email)	Your Clincard Balance

### **Visit Reminder (SMS & Email)**

Schedule	3 days and 1 day before appointment date
Message Structure	Hi <a href="#">[FIRST NAME]</a> , you have an appointment with Dr. <a href="#">[INVESTIGATOR LAST NAME]</a> on <a href="#">[DATE]</a> at <a href="#">[TIME]</a> . Please contact <a href="#">[SC FIRST NAME]</a> at <a href="#">[SC TELEPHONE]</a> if you have any questions or need to reschedule.
Message Example	Hi Sam, you have an appointment with Dr. Samar on 01/06/2011 at 11:30 am. Please contact Candice at 215-880-0715 if you have any questions or need to reschedule.
Subj. Line (Email)	Your Next Appointment with Dr. Samar

### **How do I stop this service, or "Opt-out"?**

If at any time, you wish to no longer participate in any part of the Clincard program, you may request your study coordinator to discontinue you from it. The study coordinator in turn, will remove your information from the secure computer system and the option you no longer wish to receive for this study will cease. This decision will not affect your actual study participation.

### **Do I have to pay for the text messages?**

The cost of messages will vary depending on your network carrier and on your per message transaction cost. You can consult your network carrier regarding your per message transaction cost.

### **Information that will be shared**

In order to participate in this program as a part of the research study to determine the safety and effectiveness of the study drug, Greenphire will collect information about you, including name, address, telephone number, next appointment date, date of birth, email address, if applicable, and your 6 digit subject ID code. All information is stored in a secure fashion and will be deleted from Greenphire's system once the study has been completed and the funds on the card have been exhausted. Your information will not be shared with any third parties and will be kept confidential.

## **Risk**

For these uses, the Sponsor may share this with others involved in these activities, as long as they agree to only use the personal data as described here. Once the research team shares personal data about you with others, Federal privacy law may no longer protect it.

## **Will the study sponsor or Greenphire be able to guarantee that I will receive all of the text messages sent as part of the service?**

No. The text messaging vendor will send the message to your cell phone number, but the text messaging vendor cannot prevent disruptions in Internet traffic or guarantee that your cell phone service provider will deliver the message to your cell phone. A number of things could prevent the text message from being delivered to your cell phone, including technical difficulties. If you are out of your coverage area for a number of days, or if you do not turn on your cell phone for a number of days, your cell phone service provider may not deliver text messages that come in during that period. Thus, it is important that if you elect to use this service, you use it together with other reminders.

## **CONSENT TO PARTICIPATE IN THE CLINCARD REIMBURSEMENT CARD SERVICE**

If you would like to participate in the Clincard reimbursement card program please sign this consent form in the spaces provided below. Please take as much time as you like to decide. Please ask your study doctor any questions you may have.

You will receive a signed copy of this consent form addendum.

### **By signing below, I agree that:**

- I have been told that all other conditions of the study remain the same. I have reviewed the consent form for the original study and continue to agree to all terms stated in it.
- I have read this consent form addendum.
- I understand the participating in the Clincard program is optional.
- I give permission to use and share my information about me as described in this form.
- I may choose not to use the Clincard program for this study by telling the study doctor. I will not be penalized or lose any benefits to which I am otherwise entitled.

- I would like to participate in the Clincard program and have read the disclosures and descriptions above.
- I have had the chance to ask questions and all of my questions have been answered

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Person Conducting Informed Consent Discussion

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### **CONSENT TO PARTICIPATE IN THE TEXT MESSAGING SERVICE**

- I have been told that all other conditions of the study remain the same. I have reviewed the consent form for the original study and continue to agree to all terms stated in it.
- I have read this consent form addendum.
- I understand that using the text message service for this study is optional.
- I give permission to use and share my information about me as described in this form.
- I may choose not to use the text message service for this study by telling the study doctor. I will not be penalized or lose any benefits to which I am otherwise entitled.
- I would like to receive the optional text message service and have read the disclosures and descriptions above.
- I have had the chance to ask questions and all of my questions have been answered

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Person Conducting Informed Consent Discussion

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**CONSENT TO PARTICIPATE IN THE EMAIL SERVICE**

- I have been told that all other conditions of the study remain the same. I have reviewed the consent form for the original study and continue to agree to all terms stated in it.
- I have read this consent form addendum.
- I understand that using the email service for this study is optional.
- I give permission to use and share my information about me as described in this form.
- I may choose not to use the email service for this study by telling the study doctor. I will not be penalized or lose any benefits to which I am otherwise entitled.
- I would like to receive the email reminder service and have read the disclosures and descriptions above.
- I have had the chance to ask questions and all of my questions have been answered

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Person Conducting Informed Consent Discussion

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_