Safety and Efficacy of an Investigational Drug in Human Immunodeficiency Virus (HIV)-Infected Patients Failing Current Antiretroviral Therapies (0518-005)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00105157

First received: March 8, 2005
Last updated: December 3, 2015
Last verified: December 2015
History of Changes

Purpose

This study will investigate the safety and efficacy of different doses of an investigational drug (MK0518) as a therapy for HIV-infected patients failing current antiretroviral therapies.

Condition	Intervention	Phase
HIV Infections Acquired Immunodeficiency Syndrome	Drug: Comparator: MK0518 Drug: MK0518 Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: Multicenter Study to Evaluate the Safety and Efficacy of MK0518 in Combination With An Optimized Background Therapy (OBT), Versus OBT Alone, in HIV-Infected Patients With Documented Resistance

Resource links provided by NLM:

MedlinePlus related topics: HIV/AIDS

Drug Information available for: Raltegravir Raltegravir potassium

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 24 [Time Frame: Baseline and Week 24]
  [Designated as safety issue: No]

  Mean change from baseline at Week 24 in HIV RNA (log10 copies/mL) in all patients

Secondary Outcome Measures:

- Number of Patients With Virologic Responses at Week 24 [Time Frame: 24 weeks] [Designated as safety issue: No]

  Number of patients who achieve HIV RNA <400 copies/mL; HIV RNA level <50 copies/mL at Week 24; or reduction from baseline in HIV RNA (log10 copies/mL) exceeding 1.0 log10 copies/mL at Week 24; at Week 24

- Change From Baseline in CD4 Cell Count at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  Mean change from baseline at Week 24 in CD4 Cell Count (cells/mm3)

- Number of Patients With Clinical Adverse Experiences (CAEs) at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]

  An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product

- Number of Patients With Serious CAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose

- Number of Patients With Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]

  Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs

- Number of Patients With Serious Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose. Drug-related are as assessed by an investigator who is a qualified physician according to his/her best clinical judgment.

- Number of Patients That Died by 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With CAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Serious CAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Serious Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks]
  [Designated as safety issue: Yes]
- Number of Patients With Laboratory Adverse Experiences (LAEs) at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]

  A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product

- Number of Patients With Drug-related LAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]

  Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs

- Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 48 Weeks [Time Frame: 48 weeks]
  [Designated as safety issue: Yes]
- Number of Patients Discontinued With Drug-related LAEs at 48 Weeks [Time Frame: 48 weeks] [Designated as safety issue: Yes]
- Number of Patients With Clinical Adverse Experiences (CAEs) at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]

  An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product

- Number of Patients With Serious CAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is

an overdose

- Number of Patients With Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]

  Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs

- Number of Patients With Serious Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose. Drug-related are as assessed by an investigator who is a qualified physician according to his/her best clinical judgment.

- Number of Patients That Died by 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With CAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Serious CAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Serious Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]
- Number of Patients With Laboratory Adverse Experiences (LAEs) at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]

  A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product

- Number of Patients With Drug-related LAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]

  Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs

- Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]
- Number of Patients Discontinued With Drug-related LAEs at 96 Weeks [Time Frame: 96 weeks] [Designated as safety issue: Yes]
- Number of Patients With Clinical Adverse Experiences (CAEs) at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

  An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product

- Number of Patients With Serious CAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose

- Number of Patients With Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

  Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs

- Number of Patients With Serious Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose. Drug-related are as assessed by an investigator who is a qualified physician according to his/her best clinical judgment.

- Number of Patients That Died by 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With CAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Serious CAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]
- Number of Patients That Discontinued With Serious Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]
- Number of Patients With Laboratory Adverse Experiences (LAEs) at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

  A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product

- Number of Patients With Serious LAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

Serious LAEs are any LAEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose

- Number of Patients Discontinued With Drug-related LAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]
- Number of Patients With Drug-related LAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

  Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs

- Number of Patients With Serious Drug-related LAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

  Serious LAEs are any LAEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose

- Number of Patients Discontinued With LAEs at 168 Weeks [Time Frame: 168 weeks] [Designated as safety issue: Yes]

Other Outcome Measures:

- Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 168 in Combined Substudies [Time Frame: Baseline and Week 168] [Designated as safety issue: No]

  Mean change from baseline at Week 168 in HIV RNA (log10 copies/mL) in patients from combined substudies in the double-blind plus open-label phases.

- Change From Baseline in CD4 Cell Count at Week 168 in Combined Substudies [Time Frame: Baseline and Week 168] [Designated as safety issue: No]

  Mean change from baseline at Week 168 in CD4 Cell Count (cells/mm3) in patients from combined substudies in the double-blind plus open-label phases.

Enrollment:	179
Study Start Date:	March 2005
Study Completion Date:	July 2009
Primary Completion Date:	October 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 MK0518 200 mg	Drug: Comparator: MK0518 MK0518 oral tablets 200 mg b.i.d, for 24 weeks Other Name: MK0518
Experimental: 2 MK0518 400 mg	Drug: MK0518 MK0518 oral tablets 400 mg b.i.d, for 24 weeks
Experimental: 3 MK0518 600 mg	Drug: MK0518 MK0518 oral tablets 600 mg b.i.d, for 24 weeks
Placebo Comparator: 4 Placebo	Drug: Placebo Placebo to MK0518, oral tablet b.i.d, for 24 weeks

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient must be HIV positive with Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) values that are within ranges required by the

study

- Patient must be currently on antiretroviral therapy (ART)

Exclusion Criteria:

- Patient less than 18 years of age
- Additional exclusion criteria will be discussed and identified by the study doctor

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00105157

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Grinsztejn B, Nguyen BY, Katlama C, Gatell JM, Lazzarin A, Vittecoq D, Gonzalez CJ, Chen J, Harvey CM, Isaacs RD; Protocol 005 Team. Safety and efficacy of the HIV-1 integrase inhibitor raltegravir (MK-0518) in treatment-experienced patients with multidrug-resistant virus: a phase II randomised controlled trial. Lancet. 2007 Apr 14;369(9569):1261-9.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00105157 History of Changes
Other Study ID Numbers:	**0518-005** MK**0518-005** 2005_007
Study First Received:	March 8, 2005
Results First Received:	September 14, 2009
Last Updated:	December 3, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Acquired Immunodeficiency Syndrome	Retroviridae Infections
HIV Infections	Sexually Transmitted Diseases
Immunologic Deficiency Syndromes	Sexually Transmitted Diseases, Viral
Immune System Diseases	Slow Virus Diseases
Lentivirus Infections	Virus Diseases
RNA Virus Infections	

ClinicalTrials.gov processed this record on March 10, 2016

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Safety and Efficacy of an Investigational Drug in Human Immunodeficiency Virus (HIV)-Infected Patients Failing Current Antiretroviral Therapies (0518-005)(COMPLETED)

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Sponsor:
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ClinicalTrials.gov Identifier:
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First received: March 8, 2005
Last updated: December 3, 2015
Last verified: December 2015
History of Changes

Results First Received: September 14, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	HIV Infections Acquired Immunodeficiency Syndrome
Interventions:	Drug: Comparator: MK0518 Drug: MK0518 Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Primary therapy period: 22-Apr-2005 to 09-Nov-2006

Multicenter (31) in the United States (15) and outside the United States (16)

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Patients failed prior antiretroviral therapy (HIV RNA >5000 copies/mL), and had documented resistance to at least one drug in each class of licensed oral antiretroviral therapy (Nucleoside Reverse Transcriptase inhibitors, Non-Nucleoside Reverse Transcriptase inhibitors and Protease Inhibitors). All patients must have met laboratory criteria.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Participant Flow for 3 periods

Period 1: Double-Blind (DB)

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
STARTED	44	45	45	45
Treated	43	45	45	45
COMPLETED	30	31	33	6
NOT COMPLETED	14	14	12	39
Never Treated	1	0	0	0
Adverse Event	2	0	1	1
Lack of Efficacy	11	14	11	38

Period 2: Open-Label Continuation of DB

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
STARTED	30	31	33	6
COMPLETED	23	21	24	5
NOT COMPLETED	7	10	9	1
Adverse Event	3	1	0	0
Lack of Efficacy	1	4	3	1
Lost to Follow-up	1	1	1	0
Withdrawal by Subject	0	1	3	0
Patient did not continue in extension	1	0	0	0

Patient moved/site stopped trial	**1**	**3**	**2**	**0**

Period 3: Open-Label Post Virologic Failure(OLPVF)

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
STARTED	11 [1]	13 [1]	11 [1]	37 [1]
COMPLETED	2	7	5	19
NOT COMPLETED	9	6	6	18
Adverse Event	0	0	0	1
Lack of Efficacy	7	6	5	10
Lost to Follow-up	1	0	0	1
Withdrawal by Subject	0	0	0	5
Patient moved/Site stopped trial	1	0	1	1

[1] Number of Patients appropriate for and who consented to enter the OLPVF

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Total	Total of all reporting groups

Baseline Measures

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo	Total
Number of Participants					

[units: participants]	**43**	**45**	**45**	**45**	**178**
Age [units: years] Mean (Full Range)	**44.0 (18 to 57)**	**45.1 (32 to 69)**	**43.8 (25 to 63)**	**43.3 (29 to 59)**	**44.1 (18 to 69)**
Gender [units: participants]					
Female	**7**	**5**	**4**	**5**	**21**
Male	**36**	**40**	**41**	**40**	**157**
Race/Ethnicity, Customized [units: participants]					
White	**36**	**35**	**32**	**33**	**136**
Black	**3**	**5**	**7**	**5**	**20**
Asian	**0**	**0**	**2**	**1**	**3**
Hispanic	**4**	**5**	**4**	**5**	**18**
Others	**0**	**0**	**0**	**1**	**1**
Cluster of Differentiation 4 (CD4) Cell Count [units: Cells/mm3] Mean (Full Range)	**244.9 (30 to 1153)**	**220.6 (68 to 673)**	**220.4 (30 to 663)**	**274.0 (37 to 880)**	**239.9 (30 to 1153)**
Plasma HIV RNA [units: log10 copies/mL] Mean (Full Range)	**4.6 (3.5 to 5.9)**	**4.8 (3.7 to 5.9)**	**4.7 (3.8 to 5.8)**	**4.7 (3.6 to 5.8)**	**4.7 (3.5 to 5.9)**
Plasma Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) [units: Copies/mL] Mean (Full Range)	**44642.6 (3000 to 750000)**	**59107.9 (4770 to 750000)**	**49064.8 (7030 to 589000)**	**47432.6 (3630 to 611000)**	**49841.6 (3000 to 750000)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Primary
Measure Title	Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 24
Measure Description	Mean change from baseline at Week 24 in HIV RNA (log10 copies/mL) in all patients
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Observed mean change from baseline in log10 Plasma HIV RNA for each group was calculated using the conventional imputation (replace HIV RNA <400 copies/mL by 400 copies/mL if signal detected, or 200 copies/mL if signal not detected). Missing values: baseline-carry-forward for all failures or discontinued due to lack of efficacy

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 24 [units: HIV RNA (log10 copies/mL)] Mean (95% Confidence Interval)	**-1.80 (-2.10 to -1.50)**	**-1.87 (-2.16 to -1.58)**	**-1.84 (-2.10 to -1.58)**	**-0.35 (-0.61 to -0.09)**

No statistical analysis provided for Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 24

2. Secondary: Number of Patients With Virologic Responses at Week 24 [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Virologic Responses at Week 24
Measure Description	Number of patients who achieve HIV RNA <400 copies/mL; HIV RNA level <50 copies/mL at Week 24; or reduction from baseline in HIV RNA (log10 copies/mL) exceeding 1.0 log10 copies/mL at Week 24; at Week 24
Time Frame	24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg

	b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Virologic Responses at Week 24 [units: Participants]				
HIV RNA <400 copies/mL	**30**	**32**	**32**	**7**
HIV RNA <50 copies/mL	**28**	**25**	**30**	**6**
>1.0 log10 Drop in HIV RNA	**33**	**36**	**36**	**8**

No statistical analysis provided for Number of Patients With Virologic Responses at Week 24

3. Secondary: Change From Baseline in CD4 Cell Count at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in CD4 Cell Count at Week 24
Measure Description	Mean change from baseline at Week 24 in CD4 Cell Count (cells/mm3)
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Observed failure approach assuming baseline-carry-forward for all failures, exclude other missing values. Baseline CD4 Cell Count (cells/mm3) was carried forward for patients who discontinued assigned therapy due to lack of efficacy.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after

	completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Change From Baseline in CD4 Cell Count at Week 24 [units: CD4 Cell Count (cells/mm3)] Mean (95% Confidence Interval)	**62.9 (27.8 to 97.9)**	**112.8 (75.7 to 150.0)**	**94.1 (60.1 to 128.0)**	**5.4 (-9.9 to 20.7)**

No statistical analysis provided for Change From Baseline in CD4 Cell Count at Week 24

4. Secondary: Number of Patients With Clinical Adverse Experiences (CAEs) at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Clinical Adverse Experiences (CAEs) at 48 Weeks
Measure Description	An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Clinical Adverse Experiences (CAEs) at 48 Weeks [units: Participants]				
With CAEs	**37**	**37**	**41**	**37**
Without CAEs	**6**	**8**	**4**	**8**

No statistical analysis provided for Number of Patients With Clinical Adverse Experiences (CAEs) at 48 Weeks

5. Secondary: Number of Patients With Serious CAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Serious CAEs at 48 Weeks
Measure Description	Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**

Number of Patients With Serious CAEs at 48 Weeks [units: Participants]				
With Serious CAEs	**3**	**7**	**4**	**3**
Without Serious CAEs	**40**	**38**	**41**	**42**

No statistical analysis provided for Number of Patients With Serious CAEs at 48 Weeks

6. Secondary: Number of Patients With Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Drug-related CAEs at 48 Weeks
Measure Description	Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Drug-related CAEs at 48 Weeks [units: Participants]				
With Drug-Related CAEs	**18**	**19**	**24**	**24**

Without Drug-Related CAEs	**25**	**26**	**21**	**21**

No statistical analysis provided for Number of Patients With Drug-related CAEs at 48 Weeks

7. Secondary: Number of Patients With Serious Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Serious Drug-related CAEs at 48 Weeks
Measure Description	Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose. Drug-related are as assessed by an investigator who is a qualified physician according to his/her best clinical judgment.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Serious Drug-related CAEs at 48 Weeks [units: Participants]				
With Serious Drug-Related CAEs	**1**	**0**	**1**	**2**
Without Serious Drug-Related CAEs	**42**	**45**	**44**	**43**

No statistical analysis provided for Number of Patients With Serious Drug-related CAEs at 48 Weeks

8. Secondary: Number of Patients That Died by 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Died by 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Died by 48 Weeks [units: Participants]				
Died	**1**	**0**	**1**	**0**
Did not Die	**42**	**45**	**44**	**45**

No statistical analysis provided for Number of Patients That Died by 48 Weeks

9. Secondary: Number of Patients That Discontinued With CAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary

Measure Title	Number of Patients That Discontinued With CAEs at 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With CAEs at 48 Weeks [units: Participants]				
Discontinued With CAEs	**1**	**0**	**1**	**1**
Did Not Discontinue With CAEs	**42**	**45**	**44**	**44**

No statistical analysis provided for Number of Patients That Discontinued With CAEs at 48 Weeks

10. Secondary: Number of Patients That Discontinued With Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Drug-related CAEs at 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Drug-related CAEs at 48 Weeks [units: Participants]				
Discontinued With Drug-related CAEs	**0**	**0**	**0**	**1**
Did Not Discontinue With Drug-related CAEs	**43**	**45**	**45**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Drug-related CAEs at 48 Weeks

11. Secondary: Number of Patients That Discontinued With Serious CAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Serious CAEs at 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Serious CAEs at 48 Weeks [units: Participants]				
Discontinued With Serious CAEs	**1**	**0**	**1**	**1**
Did Not Discontinue With Serious CAEs	**42**	**45**	**44**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Serious CAEs at 48 Weeks

12. Secondary: Number of Patients That Discontinued With Serious Drug-related CAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Serious Drug-related CAEs at 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all

	patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Serious Drug-related CAEs at 48 Weeks [units: Participants]				
Discontinued With Serious Drug-related CAEs	**0**	**0**	**0**	**1**
Did Not Discontinue With Serious Drug-related CAEs	**43**	**45**	**45**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Serious Drug-related CAEs at 48 Weeks

13. Secondary: Number of Patients With Laboratory Adverse Experiences (LAEs) at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Laboratory Adverse Experiences (LAEs) at 48 Weeks
Measure Description	A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.

MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Laboratory Adverse Experiences (LAEs) at 48 Weeks [units: Participants]				
With LAEs	**10**	**12**	**14**	**11**
Without LAEs	**33**	**33**	**31**	**34**

No statistical analysis provided for Number of Patients With Laboratory Adverse Experiences (LAEs) at 48 Weeks

14. Secondary: Number of Patients With Drug-related LAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Drug-related LAEs at 48 Weeks
Measure Description	Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400

	mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Drug-related LAEs at 48 Weeks [units: Participants]				
With Drug-related LAEs	**7**	**8**	**7**	**8**
Without Drug-related LAEs	**36**	**37**	**38**	**37**

No statistical analysis provided for Number of Patients With Drug-related LAEs at 48 Weeks

15. Secondary: Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo

Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 48 Weeks [units: Participants]				
Discontinued With LAEs	**1**	**0**	**0**	**0**
Did Not Discontinue With LAEs	**42**	**45**	**45**	**45**

No statistical analysis provided for Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 48 Weeks

16. Secondary: Number of Patients Discontinued With Drug-related LAEs at 48 Weeks [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Number of Patients Discontinued With Drug-related LAEs at 48 Weeks
Measure Description	No text entered.
Time Frame	48 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients Discontinued With Drug-related LAEs at 48 Weeks [units: Participants]				

Discontinued With Drug-Related LAEs	**1**	**0**	**0**	**0**
Did Not Discontinue With Drug-Related LAEs	**42**	**45**	**45**	**45**

No statistical analysis provided for Number of Patients Discontinued With Drug-related LAEs at 48 Weeks

17. Secondary: Number of Patients With Clinical Adverse Experiences (CAEs) at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Clinical Adverse Experiences (CAEs) at 96 Weeks
Measure Description	An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Clinical Adverse Experiences (CAEs) at 96 Weeks [units: Participants]				
With CAEs	**43**	**42**	**45**	**38**
Without CAEs	**0**	**3**	**0**	**7**

No statistical analysis provided for Number of Patients With Clinical Adverse Experiences (CAEs) at 96 Weeks

18. Secondary: Number of Patients With Serious CAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Serious CAEs at 96 Weeks
Measure Description	Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Serious CAEs at 96 Weeks [units: Participants]				
With Serious CAEs	**4**	**9**	**5**	**3**
Without Serious CAEs	**39**	**36**	**40**	**42**

No statistical analysis provided for Number of Patients With Serious CAEs at 96 Weeks

19. Secondary: Number of Patients With Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Drug-related CAEs at 96 Weeks
Measure Description	Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Drug-related CAEs at 96 Weeks [units: Participants]				
With drug-related CAEs	**24**	**25**	**28**	**26**
Without drug-related CAEs	**19**	**20**	**17**	**19**

No statistical analysis provided for Number of Patients With Drug-related CAEs at 96 Weeks

20. Secondary: Number of Patients With Serious Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Serious Drug-related CAEs at 96 Weeks
Measure Description	Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital

	anomaly/birth defect; or Is a cancer; or Is an overdose. Drug-related are as assessed by an investigator who is a qualified physician according to his/her best clinical judgment.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Serious Drug-related CAEs at 96 Weeks [units: Participants]				
With Serious Drug-Related CAEs	**1**	**0**	**1**	**2**
Without Serious Drug-Related CAEs	**42**	**45**	**44**	**43**

No statistical analysis provided for Number of Patients With Serious Drug-related CAEs at 96 Weeks

21. Secondary: Number of Patients That Died by 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Died by 96 Weeks
Measure Description	No text entered.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Died by 96 Weeks [units: Participants]				
Died	**2**	**1**	**1**	**0**
Did Not Die	**41**	**44**	**44**	**45**

No statistical analysis provided for Number of Patients That Died by 96 Weeks

22. Secondary: Number of Patients That Discontinued With CAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With CAEs at 96 Weeks
Measure Description	No text entered.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With CAEs at 96 Weeks [units: Participants]				
Discontinued With CAEs	**2**	**1**	**1**	**1**
Did Not Discontinue With CAEs	**41**	**44**	**44**	**44**

No statistical analysis provided for Number of Patients That Discontinued With CAEs at 96 Weeks

23. Secondary: Number of Patients That Discontinued With Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Drug-related CAEs at 96 Weeks
Measure Description	No text entered.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Drug-related CAEs at 96 Weeks [units: Participants]				
Discontinued With Drug-Related CAEs	**0**	**0**	**0**	**1**
Did Not Discontinue With Drug-Related CAEs	**43**	**45**	**45**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Drug-related CAEs at 96 Weeks

24. Secondary: Number of Patients That Discontinued With Serious CAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Serious CAEs at 96 Weeks
Measure Description	No text entered.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Serious CAEs at 96 Weeks [units: Participants]				
Discontinued With Serious CAEs	**2**	**1**	**1**	**1**
Did Not Discontinue With Serious CAEs	**41**	**44**	**44**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Serious CAEs at 96 Weeks

25. Secondary: Number of Patients That Discontinued With Serious Drug-related CAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Serious Drug-related CAEs at 96 Weeks
Measure Description	No text entered.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Serious Drug-related CAEs at 96 Weeks [units: Participants]				
Discontinued With Serious Drug-related CAEs	**0**	**0**	**0**	**1**
Did Not Discontinue With Serious Drug-related CAEs	**43**	**45**	**45**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Serious Drug-related CAEs at 96 Weeks

26. Secondary: Number of Patients With Laboratory Adverse Experiences (LAEs) at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Laboratory Adverse Experiences (LAEs) at 96 Weeks
Measure Description	A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed				

[units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Laboratory Adverse Experiences (LAEs) at 96 Weeks [units: Participants]				
With LAEs	**12**	**15**	**17**	**12**
Without LAEs	**31**	**30**	**28**	**33**

No statistical analysis provided for Number of Patients With Laboratory Adverse Experiences (LAEs) at 96 Weeks

27. Secondary: Number of Patients With Drug-related LAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Drug-related LAEs at 96 Weeks
Measure Description	Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Drug-related LAEs at 96 Weeks [units: Participants]				
With Drug-Related LAEs	**9**	**9**	**11**	**8**

Without Drug-Related LAEs	**34**	**36**	**34**	**37**

No statistical analysis provided for Number of Patients With Drug-related LAEs at 96 Weeks

28. Secondary: Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 96 Weeks
Measure Description	No text entered.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 96 Weeks [units: Participants]				
Discontinued With LAEs	**1**	**1**	**0**	**0**
Did Not Discontinue With LAEs	**42**	**44**	**45**	**45**

No statistical analysis provided for Number of Patients Discontinued With Laboratory Adverse Experiences (LAEs) at 96 Weeks

29. Secondary: Number of Patients Discontinued With Drug-related LAEs at 96 Weeks [Time Frame: 96 weeks]

Measure Type	Secondary
Measure Title	Number of Patients Discontinued With Drug-related LAEs at 96 Weeks
Measure Description	No text entered.
Time Frame	96 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients Discontinued With Drug-related LAEs at 96 Weeks [units: Participants]				
Discontinued With Drug-related LAEs	**1**	**1**	**0**	**0**
Did Not Discontinue With Drug-related LAEs	**42**	**44**	**45**	**45**

No statistical analysis provided for Number of Patients Discontinued With Drug-related LAEs at 96 Weeks

30. Secondary: Number of Patients With Clinical Adverse Experiences (CAEs) at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary

Measure Title	Number of Patients With Clinical Adverse Experiences (CAEs) at 168 Weeks
Measure Description	An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Clinical Adverse Experiences (CAEs) at 168 Weeks [units: Participants]				
With CAEs	**43**	**43**	**45**	**38**
Without CAEs	**0**	**2**	**0**	**7**

No statistical analysis provided for Number of Patients With Clinical Adverse Experiences (CAEs) at 168 Weeks

31. Secondary: Number of Patients With Serious CAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Serious CAEs at 168 Weeks
Measure Description	Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent

	or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Serious CAEs at 168 Weeks [units: Participants]				
With Serious CAEs	**6**	**13**	**7**	**3**
Without Serious CAEs	**37**	**32**	**38**	**42**

No statistical analysis provided for Number of Patients With Serious CAEs at 168 Weeks

32. Secondary: Number of Patients With Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Drug-related CAEs at 168 Weeks
Measure Description	Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Drug-related CAEs at 168 Weeks [units: Participants]				
With Drug-Related CAEs	**27**	**27**	**30**	**26**
Without Drug-Related CAEs	**16**	**18**	**15**	**19**

No statistical analysis provided for Number of Patients With Drug-related CAEs at 168 Weeks

33. Secondary: Number of Patients With Serious Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Serious Drug-related CAEs at 168 Weeks
Measure Description	Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose. Drug-related are as assessed by an investigator who is a qualified physician according to his/her best clinical judgment.
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Serious Drug-related CAEs at 168 Weeks [units: Participants]				
With Serious Drug-Related CAEs	**2**	**0**	**2**	**2**
Without Serious Drug-Related CAEs	**41**	**45**	**43**	**43**

No statistical analysis provided for Number of Patients With Serious Drug-related CAEs at 168 Weeks

34. Secondary: Number of Patients That Died by 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Died by 168 Weeks
Measure Description	No text entered.
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Died by 168 Weeks [units: Participants]				
Died	**3**	**1**	**1**	**0**
Did not Die	**40**	**44**	**44**	**45**

No statistical analysis provided for Number of Patients That Died by 168 Weeks

35. Secondary: Number of Patients That Discontinued With CAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With CAEs at 168 Weeks
Measure Description	No text entered.
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With CAEs at 168 Weeks [units: Participants]				
Discontinued With CAEs	**3**	**1**	**1**	**1**
Did Not Discontinue With CAEs	**40**	**44**	**44**	**44**

No statistical analysis provided for Number of Patients That Discontinued With CAEs at 168 Weeks

36. Secondary: Number of Patients That Discontinued With Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Drug-related CAEs at 168 Weeks
Measure Description	No text entered.
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after

	completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Drug-related CAEs at 168 Weeks [units: Participants]				
Discontinued With Drug-related CAEs	**0**	**0**	**0**	**1**
Did Not Discontinue With Drug-related CAEs	**43**	**45**	**45**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Drug-related CAEs at 168 Weeks

37. Secondary: Number of Patients That Discontinued With Serious CAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Serious CAEs at 168 Weeks
Measure Description	No text entered.
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	43	45	45	45
Number of Patients That Discontinued With Serious CAEs at 168 Weeks [units: Participants]				
Discontinued With Serious CAEs	3	1	1	1
Did Not Discontinue With Serious CAEs	40	44	44	44

No statistical analysis provided for Number of Patients That Discontinued With Serious CAEs at 168 Weeks

38. Secondary: Number of Patients That Discontinued With Serious Drug-related CAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients That Discontinued With Serious Drug-related CAEs at 168 Weeks
Measure Description	No text entered.
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo

Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients That Discontinued With Serious Drug-related CAEs at 168 Weeks [units: Participants]				
Discontinued With Serious Drug-related CAEs	**0**	**0**	**0**	**1**
Did Not Discontinue With Serious Drug-related CAEs	**43**	**45**	**45**	**44**

No statistical analysis provided for Number of Patients That Discontinued With Serious Drug-related CAEs at 168 Weeks

39. Secondary: Number of Patients With Laboratory Adverse Experiences (LAEs) at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Laboratory Adverse Experiences (LAEs) at 168 Weeks
Measure Description	A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Laboratory Adverse Experiences (LAEs)				

at 168 Weeks [units: Participants]				
With LAEs	**17**	**16**	**18**	**12**
Without LAEs	**26**	**29**	**27**	**33**

No statistical analysis provided for Number of Patients With Laboratory Adverse Experiences (LAEs) at 168 Weeks

40. Secondary: Number of Patients With Serious LAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Serious LAEs at 168 Weeks
Measure Description	Serious LAEs are any LAEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Serious LAEs at 168 Weeks [units: Participants]				
With Serious LAEs	**1**	**0**	**1**	**0**

Without Serious LAEs	**42**	**45**	**44**	**45**

No statistical analysis provided for Number of Patients With Serious LAEs at 168 Weeks

41. Secondary: Number of Patients Discontinued With Drug-related LAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients Discontinued With Drug-related LAEs at 168 Weeks
Measure Description	No text entered.
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients Discontinued With Drug-related LAEs at 168 Weeks [units: Participants]				
Discontinued With Drug-Related LAEs	**2**	**0**	**0**	**0**
Did Not Discontinue With Drug-Related LAEs	**41**	**45**	**45**	**45**

No statistical analysis provided for Number of Patients Discontinued With Drug-related LAEs at 168 Weeks

42. Secondary: Number of Patients With Drug-related LAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Drug-related LAEs at 168 Weeks
Measure Description	Patients with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Drug-related LAEs at 168 Weeks [units: Participants]				
With Drug-related LAEs	**13**	**10**	**11**	**9**
Without Drug-related LAEs	**30**	**35**	**34**	**36**

No statistical analysis provided for Number of Patients With Drug-related LAEs at 168 Weeks

43. Secondary: Number of Patients With Serious Drug-related LAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary

Measure Title	Number of Patients With Serious Drug-related LAEs at 168 Weeks
Measure Description	Serious LAEs are any LAEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose
Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients With Serious Drug-related LAEs at 168 Weeks [units: Participants]				
With Drug-related LAEs	**1**	**0**	**1**	**0**
Without Drug-related LAEs	**42**	**45**	**44**	**45**

No statistical analysis provided for Number of Patients With Serious Drug-related LAEs at 168 Weeks

44. Secondary: Number of Patients Discontinued With LAEs at 168 Weeks [Time Frame: 168 weeks]

Measure Type	Secondary
Measure Title	Number of Patients Discontinued With LAEs at 168 Weeks
Measure Description	No text entered.

Time Frame	168 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication were included in the analysis (All Patients as Treated approach). Data include patients from the double-blind plus open-label phases.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**45**	**45**	**45**
Number of Patients Discontinued With LAEs at 168 Weeks [units: Participants]				
Discontinued With LAEs	**2**	**0**	**0**	**0**
Did Not Discontinue With LAEs	**41**	**45**	**45**	**45**

No statistical analysis provided for Number of Patients Discontinued With LAEs at 168 Weeks

45. Post-Hoc: Number of Patients With Virologic Responses at Week 168 in Combined Substudies [Time Frame: 168 weeks]

Measure Type	Post-Hoc
Measure Title	Number of Patients With Virologic Responses at Week 168 in Combined Substudies
Measure Description	Number of patients who achieve HIV RNA <400 copies/mL; HIV RNA level <50 copies/mL at Week 168; or reduction from baseline in HIV RNA (log10 copies/mL) exceeding 1.0 log10 copies/mL at Week 168.
Time Frame	168 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis population is based on the modified intent to treat (MITT) approach, where patients are included in the treatment group to which they were randomized. Patients who were randomized but never dosed are not included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	**MK0518 400 mg b.i.d.**	**MK0518 600 mg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**43**	**43**	**44**	**45**
Number of Patients With Virologic Responses at Week 168 in Combined Substudies [units: Participants]				
HIV RNA <400 copies/mL	**21**	**15**	**22**	**5**
HIV RNA <50 copies/mL	**20**	**13**	**19**	**5**
>1.0 log10 Drop in HIV RNA	**22**	**15**	**23**	**5**

No statistical analysis provided for Number of Patients With Virologic Responses at Week 168 in Combined Substudies

46. Other Pre-specified: Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 168 in Combined Substudies [Time Frame: Baseline and Week 168]

Measure Type	Other Pre-specified
Measure Title	Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 168 in Combined Substudies
Measure Description	Mean change from baseline at Week 168 in HIV RNA (log10 copies/mL) in patients from combined substudies in the double-blind plus open-label phases.
Time Frame	Baseline and Week 168
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Analysis population is based on the modified intent to treat (MITT) approach, where patients are included in the treatment group to which they were randomized. Patients who were randomized but never dosed are not included in the analysis.

Reporting Groups

	Description
MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**37**	**38**	**40**	**44**
Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 168 in Combined Substudies [units: HIV RNA (log10 copies/mL)] Mean (95% Confidence Interval)	**-1.67 (-2.17 to -1.18)**	**-1.32 (-1.88 to -0.77)**	**-1.66 (-2.15 to -1.17)**	**-0.33 (-0.61 to -0.04)**

No statistical analysis provided for Change From Baseline in Plasma HIV RNA (log10 Copies/mL) at Week 168 in Combined Substudies

47. Other Pre-specified: Change From Baseline in CD4 Cell Count at Week 168 in Combined Substudies [Time Frame: Baseline and Week 168]

Measure Type	Other Pre-specified
Measure Title	Change From Baseline in CD4 Cell Count at Week 168 in Combined Substudies
Measure Description	Mean change from baseline at Week 168 in CD4 Cell Count (cells/mm3) in patients from combined substudies in the double-blind plus open-label phases.
Time Frame	Baseline and Week 168
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Analysis population is based on the modified intent to treat (MITT) approach, where patients are included in the treatment group to which they were randomized. Patients who were randomized but never dosed are not included in the analysis.

Reporting Groups

	Description

MK0518 200 mg b.i.d.	Optimized background antiretroviral therapy (OBT), if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 200 mg twice a day (b.i.d.). Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
MK0518 400 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 400 mg b.i.d.
MK0518 600 mg b.i.d.	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 600 mg b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Measured Values

	MK0518 200 mg b.i.d.	MK0518 400 mg b.i.d.	MK0518 600 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**36**	**38**	**39**	**44**
Change From Baseline in CD4 Cell Count at Week 168 in Combined Substudies [units: CD4 Cell Count (cells/mm3)] Mean (95% Confidence Interval)	**96.9 (58.7 to 135.1)**	**107.7 (49.4 to 165.9)**	**147.4 (86.5 to 208.3)**	**25.5 (-1.1 to 52.0)**

No statistical analysis provided for Change From Baseline in CD4 Cell Count at Week 168 in Combined Substudies

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	168 weeks: Due to a 3:1 randomization of MK0518 to placebo and more discontinuations for placebo in the double-blind phase, exposure for MK0518 and placebo differs significantly with follow-up times of 336.3 and 39.7 patient-years, respectively.
Additional Description	AEs were assessed by the investigators.

Reporting Groups

	Description
MK0518	Includes patients from the MK0518 200 mg, 400 mg, and 600 mg b.i.d. dose groups. Patients who completed at least 24 weeks of double-blind therapy without virologic failure entered the open-label phase to receive open-label MK0518 400 mg b.i.d.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Serious Adverse Events

	MK0518	Placebo
Total, serious adverse events		
# participants affected / at risk	**28/133 (21.05%)**	**3/45 (6.67%)**
Blood and lymphatic system disorders		

Anaemia [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Lymphadenopathy [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Cardiac disorders		
Acute Myocardial Infarction [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Atrioventricular Block Complete [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Bradycardia [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Cardio-Respiratory Arrest [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Coronary Artery Disease [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**0/45 (0.00%)**
Myocardial Infarction [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**0/45 (0.00%)**
Eye disorders		
Photophobia [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Gastrointestinal disorders		
Anogenital Dysplasia [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Haematemesis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Haematochezia [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Irritable Bowel Syndrome [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Pancreatitis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Pancreatitis Acute [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Varices Oesophageal [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
General disorders		
Oedema Peripheral [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Pyrexia [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**0/45 (0.00%)**
Hepatobiliary disorders		

Bile Duct Obstruction [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Cholecystitis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Portal Hypertension [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Infections and infestations		
Anogenital Warts [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Bronchitis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Cellulitis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Herpes Simplex [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Herpes Zoster [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Leishmaniasis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Pneumonia [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**0/45 (0.00%)**
Postoperative Wound Infection [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Sepsis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Splenic Abscess [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Staphylococcal Abscess [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Staphylococcal Infection [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Tracheobronchitis [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Injury, poisoning and procedural complications		
Accidental Overdose [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Hip Fracture [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Laceration [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Investigations		

Lipase Increased [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Platelet Count Decreased [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Metabolism and nutrition disorders		
Metabolic Acidosis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Anal Cancer [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Anal Cancer Stage 0 [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**0/45 (0.00%)**
Basal Cell Carcinoma [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Hodgkin's Disease [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Nervous system disorders		
Facial Palsy [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Headache [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Lacunar Infarction [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Renal and urinary disorders		
Nephrolithiasis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Renal Failure [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**0/45 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Interstitial Lung Disease [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Lung Disorder [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Pleural Effusion [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**
Skin and subcutaneous tissue disorders		
Lipoatrophy [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Rash [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**

Vascular disorders		
Shock * 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/45 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	168 weeks: Due to a 3:1 randomization of MK0518 to placebo and more discontinuations for placebo in the double-blind phase, exposure for MK0518 and placebo differs significantly with follow-up times of 336.3 and 39.7 patient-years, respectively.
Additional Description	AEs were assessed by the investigators.

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
MK0518	Includes patients from the MK0518 200 mg, 400 mg, and 600 mg b.i.d. dose groups. Patients who completed at least 24 weeks of double-blind therapy without virologic failure entered the open-label phase to receive open-label MK0518 400 mg b.i.d.
Placebo	OBT, if possible, based on screening genotypic/phenotypic resistance and past treatment history and MK0518 matching placebo b.i.d.. Once the Phase III dose was determined, all patients were switched to the Phase III dose (400 mg b.i.d.) after completion of at least 24 weeks double-blind therapy.

Other Adverse Events

	MK0518	**Placebo**
Total, other (not including serious) adverse events		
# participants affected / at risk	**131/133 (98.50%)**	**39/45 (86.67%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**3/133 (2.26%)**	**2/45 (4.44%)**
Lymphadenopathy * 1		
# participants affected / at risk	**11/133 (8.27%)**	**2/45 (4.44%)**
Splenomegaly * 1		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Cardiac disorders		
Arrhythmia * 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Cardiovascular Disorder * 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Ear and labyrinth disorders		

Cerumen Impaction [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Eye disorders		
Ocular Icterus [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Vision Blurred [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Gastrointestinal disorders		
Abdominal Discomfort [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**1/45 (2.22%)**
Abdominal Distension [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**1/45 (2.22%)**
Abdominal Pain [*1]		
# participants affected / at risk	**13/133 (9.77%)**	**4/45 (8.89%)**
Abdominal Pain Upper [*1]		
# participants affected / at risk	**5/133 (3.76%)**	**1/45 (2.22%)**
Anal Fissure [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Anogenital Dysplasia [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**1/45 (2.22%)**
Cheilitis [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Constipation [*1]		
# participants affected / at risk	**6/133 (4.51%)**	**1/45 (2.22%)**
Diarrhoea [*1]		
# participants affected / at risk	**29/133 (21.80%)**	**11/45 (24.44%)**
Dry Mouth [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Dyspepsia [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**5/45 (11.11%)**
Flatulence [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**2/45 (4.44%)**
Gastric Disorder [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Gastritis [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Haemorrhoids [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**1/45 (2.22%)**
Hypoaesthesia Oral [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Nausea [*1]		

# participants affected / at risk	21/133 (15.79%)	10/45 (22.22%)
Periodontitis * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Tongue Ulceration * 1		
# participants affected / at risk	4/133 (3.01%)	0/45 (0.00%)
Toothache * 1		
# participants affected / at risk	1/133 (0.75%)	2/45 (4.44%)
Vomiting * 1		
# participants affected / at risk	11/133 (8.27%)	2/45 (4.44%)
General disorders		
Asthenia * 1		
# participants affected / at risk	6/133 (4.51%)	3/45 (6.67%)
Chest Discomfort * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Chest Pain * 1		
# participants affected / at risk	4/133 (3.01%)	3/45 (6.67%)
Chills * 1		
# participants affected / at risk	2/133 (1.50%)	1/45 (2.22%)
Drug Intolerance * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Fatigue * 1		
# participants affected / at risk	14/133 (10.53%)	4/45 (8.89%)
Injection Site Inflammation * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Injection Site Nodule * 1		
# participants affected / at risk	3/133 (2.26%)	1/45 (2.22%)
Injection Site Reaction * 1		
# participants affected / at risk	12/133 (9.02%)	3/45 (6.67%)
Nodule * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Oedema Peripheral * 1		
# participants affected / at risk	7/133 (5.26%)	0/45 (0.00%)
Pain * 1		
# participants affected / at risk	4/133 (3.01%)	2/45 (4.44%)
Pyrexia * 1		
# participants affected / at risk	12/133 (9.02%)	1/45 (2.22%)
Sensation Of Pressure * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Hepatobiliary disorders		
Hepatic Steatosis * 1		
# participants affected / at risk	4/133 (3.01%)	0/45 (0.00%)

Hepatosplenomegaly [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Hyperbilirubinaemia [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Jaundice [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Immune system disorders		
Drug Hypersensitivity [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Hypersensitivity [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**1/45 (2.22%)**
Infections and infestations		
Acute Tonsillitis [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Anogenital Warts [*1]		
# participants affected / at risk	**7/133 (5.26%)**	**0/45 (0.00%)**
Bronchitis [*1]		
# participants affected / at risk	**15/133 (11.28%)**	**7/45 (15.56%)**
Candidiasis [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**0/45 (0.00%)**
Cellulitis [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Ear Infection [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Erysipelas [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Folliculitis [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Fungal Skin Infection [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**2/45 (4.44%)**
Furuncle [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**1/45 (2.22%)**
Gastroenteritis [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**1/45 (2.22%)**
Genital Herpes [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Giardiasis [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Herpes Simplex [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Herpes Virus Infection [*1]		

# participants affected / at risk	4/133 (3.01%)	0/45 (0.00%)
Herpes Zoster [*1]		
# participants affected / at risk	7/133 (5.26%)	1/45 (2.22%)
Influenza [*1]		
# participants affected / at risk	17/133 (12.78%)	2/45 (4.44%)
Nasopharyngitis [*1]		
# participants affected / at risk	17/133 (12.78%)	2/45 (4.44%)
Onychomycosis [*1]		
# participants affected / at risk	4/133 (3.01%)	2/45 (4.44%)
Oral Candidiasis [*1]		
# participants affected / at risk	5/133 (3.76%)	0/45 (0.00%)
Oral Herpes [*1]		
# participants affected / at risk	2/133 (1.50%)	2/45 (4.44%)
Papilloma Viral Infection [*1]		
# participants affected / at risk	2/133 (1.50%)	1/45 (2.22%)
Pharyngitis [*1]		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Pharyngotonsillitis [*1]		
# participants affected / at risk	1/133 (0.75%)	1/45 (2.22%)
Pneumonia [*1]		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Respiratory Tract Infection [*1]		
# participants affected / at risk	5/133 (3.76%)	2/45 (4.44%)
Sinusitis [*1]		
# participants affected / at risk	7/133 (5.26%)	1/45 (2.22%)
Sinusitis Bacterial [*1]		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Skin Infection [*1]		
# participants affected / at risk	1/133 (0.75%)	1/45 (2.22%)
Syphilis [*1]		
# participants affected / at risk	4/133 (3.01%)	0/45 (0.00%)
Tooth Abscess [*1]		
# participants affected / at risk	5/133 (3.76%)	0/45 (0.00%)
Upper Respiratory Tract Infection [*1]		
# participants affected / at risk	13/133 (9.77%)	4/45 (8.89%)
Urinary Tract Infection [*1]		
# participants affected / at risk	4/133 (3.01%)	0/45 (0.00%)
Injury, poisoning and procedural complications		
Contusion [*1]		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Excoriation [*1]		

# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Skin Laceration * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Tibia Fracture * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Investigations		
Alanine Aminotransferase Increased * 1		
# participants affected / at risk	8/133 (6.02%)	0/45 (0.00%)
Aspartate Aminotransferase Increased * 1		
# participants affected / at risk	9/133 (6.77%)	0/45 (0.00%)
Blood Alkaline Phosphatase Increased * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Blood Amylase Increased * 1		
# participants affected / at risk	6/133 (4.51%)	0/45 (0.00%)
Blood Bilirubin Increased * 1		
# participants affected / at risk	14/133 (10.53%)	2/45 (4.44%)
Blood Cholesterol Increased * 1		
# participants affected / at risk	4/133 (3.01%)	4/45 (8.89%)
Blood Creatine Phosphokinase Increased * 1		
# participants affected / at risk	14/133 (10.53%)	0/45 (0.00%)
Blood Creatinine Increased * 1		
# participants affected / at risk	4/133 (3.01%)	1/45 (2.22%)
Blood Glucose Increased * 1		
# participants affected / at risk	6/133 (4.51%)	0/45 (0.00%)
Blood Phosphorus Decreased * 1		
# participants affected / at risk	2/133 (1.50%)	2/45 (4.44%)
Blood Potassium Decreased * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Blood Testosterone Decreased * 1		
# participants affected / at risk	1/133 (0.75%)	1/45 (2.22%)
Blood Triglycerides Increased * 1		
# participants affected / at risk	6/133 (4.51%)	2/45 (4.44%)
Blood Urine Present * 1		
# participants affected / at risk	3/133 (2.26%)	2/45 (4.44%)
Lipase Increased * 1		
# participants affected / at risk	7/133 (5.26%)	0/45 (0.00%)
Low Density Lipoprotein Increased * 1		
# participants affected / at risk	4/133 (3.01%)	2/45 (4.44%)
Lymphocyte Count Decreased * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Neutrophil Count Decreased * 1		

# participants affected / at risk	4/133 (3.01%)	2/45 (4.44%)
Platelet Count Decreased * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Protein Urine Present * 1		
# participants affected / at risk	5/133 (3.76%)	1/45 (2.22%)
Weight Decreased * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
White Blood Cell Count Decreased * 1		
# participants affected / at risk	1/133 (0.75%)	1/45 (2.22%)
Metabolism and nutrition disorders		
Anorexia * 1		
# participants affected / at risk	4/133 (3.01%)	1/45 (2.22%)
Decreased Appetite * 1		
# participants affected / at risk	3/133 (2.26%)	1/45 (2.22%)
Dyslipidaemia * 1		
# participants affected / at risk	6/133 (4.51%)	0/45 (0.00%)
Hypercholesterolaemia * 1		
# participants affected / at risk	3/133 (2.26%)	1/45 (2.22%)
Musculoskeletal and connective tissue disorders		
Arthralgia * 1		
# participants affected / at risk	7/133 (5.26%)	3/45 (6.67%)
Arthritis * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Back Pain * 1		
# participants affected / at risk	10/133 (7.52%)	1/45 (2.22%)
Muscle Hypertrophy * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Muscle Spasms * 1		
# participants affected / at risk	4/133 (3.01%)	1/45 (2.22%)
Musculoskeletal Pain * 1		
# participants affected / at risk	7/133 (5.26%)	0/45 (0.00%)
Myalgia * 1		
# participants affected / at risk	8/133 (6.02%)	0/45 (0.00%)
Neck Pain * 1		
# participants affected / at risk	3/133 (2.26%)	0/45 (0.00%)
Pain In Extremity * 1		
# participants affected / at risk	10/133 (7.52%)	2/45 (4.44%)
Tendonitis * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)
Tenosynovitis * 1		
# participants affected / at risk	0/133 (0.00%)	1/45 (2.22%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Skin Papilloma [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**1/45 (2.22%)**
Nervous system disorders		
Dizziness [*1]		
# participants affected / at risk	**5/133 (3.76%)**	**0/45 (0.00%)**
Dysgeusia [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**1/45 (2.22%)**
Dysphasia [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Facial Palsy [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**2/45 (4.44%)**
Headache [*1]		
# participants affected / at risk	**21/133 (15.79%)**	**5/45 (11.11%)**
Hemicephalalgia [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Hypoaesthesia [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**1/45 (2.22%)**
Migraine [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Neuropathy Peripheral [*1]		
# participants affected / at risk	**5/133 (3.76%)**	**2/45 (4.44%)**
Paraesthesia [*1]		
# participants affected / at risk	**8/133 (6.02%)**	**0/45 (0.00%)**
Syncope [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**1/45 (2.22%)**
Psychiatric disorders		
Anxiety [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**2/45 (4.44%)**
Depression [*1]		
# participants affected / at risk	**10/133 (7.52%)**	**1/45 (2.22%)**
Insomnia [*1]		
# participants affected / at risk	**12/133 (9.02%)**	**2/45 (4.44%)**
Sleep Disorder [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**1/45 (2.22%)**
Renal and urinary disorders		
Dysuria [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**2/45 (4.44%)**
Nephrolithiasis [*1]		
# participants affected / at risk	**2/133 (1.50%)**	**1/45 (2.22%)**

Renal Cyst [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Reproductive system and breast disorders		
Benign Prostatic Hyperplasia [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Erectile Dysfunction [*1]		
# participants affected / at risk	**5/133 (3.76%)**	**0/45 (0.00%)**
Pelvic Pain [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Prostatitis [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Cough [*1]		
# participants affected / at risk	**23/133 (17.29%)**	**1/45 (2.22%)**
Dyspnoea [*1]		
# participants affected / at risk	**6/133 (4.51%)**	**0/45 (0.00%)**
Oropharyngeal Pain [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**3/45 (6.67%)**
Paranasal Sinus Hypersecretion [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Productive Cough [*1]		
# participants affected / at risk	**5/133 (3.76%)**	**0/45 (0.00%)**
Rhinitis Allergic [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Rhinorrhoea [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**2/45 (4.44%)**
Sinus Congestion [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**2/45 (4.44%)**
Sneezing [*1]		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Skin and subcutaneous tissue disorders		
Alopecia [*1]		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Dry Skin [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Dyshidrosis [*1]		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Eczema [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**1/45 (2.22%)**
Erythema [*1]		
# participants affected / at risk	**4/133 (3.01%)**	**0/45 (0.00%)**

Facial Wasting * 1		
# participants affected / at risk	**4/133 (3.01%)**	**0/45 (0.00%)**
Lipodystrophy Acquired * 1		
# participants affected / at risk	**6/133 (4.51%)**	**0/45 (0.00%)**
Night Sweats * 1		
# participants affected / at risk	**2/133 (1.50%)**	**3/45 (6.67%)**
Pruritus * 1		
# participants affected / at risk	**9/133 (6.77%)**	**1/45 (2.22%)**
Rash * 1		
# participants affected / at risk	**9/133 (6.77%)**	**1/45 (2.22%)**
Rash Macular * 1		
# participants affected / at risk	**1/133 (0.75%)**	**1/45 (2.22%)**
Rash Papular * 1		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Seborrhoeic Dermatitis * 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/45 (2.22%)**
Skin Lesion * 1		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Skin Nodule * 1		
# participants affected / at risk	**2/133 (1.50%)**	**1/45 (2.22%)**
Subcutaneous Nodule * 1		
# participants affected / at risk	**4/133 (3.01%)**	**1/45 (2.22%)**
Vascular disorders		
Hyperaemia * 1		
# participants affected / at risk	**3/133 (2.26%)**	**0/45 (0.00%)**
Hypertension * 1		
# participants affected / at risk	**13/133 (9.77%)**	**0/45 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 12.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

Due to a 3:1 randomization of MK-0518 to placebo and more discontinuations for placebo in the doubleblind phase, exposure for MK-0518 and placebo differs significantly with follow-up times of 336.3 and 39.7 patient-years, respectively.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372

Publications:

Grinsztejn B, Nguyen BY, Katlama C, Gatell JM, Lazzarin A, Vittecoq D, Gonzalez CJ, Chen J, Harvey CM, Isaacs RD; Protocol 005 Team. Safety and efficacy of the HIV-1 integrase inhibitor raltegravir (MK-0518) in treatment-experienced patients with multidrug-resistant virus: a phase II randomised controlled trial. Lancet. 2007 Apr 14;369(9569):1261-9.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00105157 History of Changes
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Last Updated:	December 3, 2015
Health Authority:	United States: Food and Drug Administration

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