

Table 30. Antiretroviral Agents Available Through Expanded Access Program (EAP)

Drug	TMC-125 (etravirine)	MK-0518
Source	1-866-889-2074 TMC125EAP@i3research.com http://www.tibotec.com/	http://www.earmrk.com
Class	Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)	Integrase Inhibitor
Dose	TMC-125 200mg twice daily + optimized background therapy (based on prior history and resistance testing)	MK-0518 400mg twice daily + optimized background therapy (based on prior history and resistance testing)
Enrollment Criteria	<p><u>Inclusion Criteria:</u></p> <ul style="list-style-type: none"> • ≥ 18 years old • Limited or no treatment options because of virologic failure or intolerance to multiple ARV regimens • Unable to use currently approved NNRTIs because of resistance and/or intolerance • Have received licenced oral therapy with each of the 3 major classes (PI, NRTIs, and NNRTI) of ARVs • Have received 2 different PI-based regimens in the past • Primary NNRTI resistance can be included if experienced with at least 2 classes of ARVs (PI, NRTI) • Have not participated in TMC-125 studies in the past • Consult expanded access protocol for list of exclusion criteria. 	<p><u>Inclusion Criteria:</u></p> <ul style="list-style-type: none"> • ≥ 16 years old • Limited or no treatment options available because of resistance (documented resistance to ≥ 1 drug in each of the 3 major classes of PI, NRTI, and NNRTI) or intolerance to multiple antiretroviral regimens • Not achieving adequate virologic suppression on current regimen • Be at risk of immunologic progression • Be clinically stable • Have not received MK-0518 in a clinical trial • Have CrCl >30 mL/min • Consult expanded access protocol for list of exclusion criteria.