

Table 2

Antiretroviral Classes with Newly Approved Drugs in Treatment-Experienced Patients

Class	Drug Name	Clinical Status	Pivotal Clinical Studies	Comments
Entry Inhibitors	Maraviroc ^a (Selzentry®)	FDA-approved	<p><u>Phase IIb/III studies (MOTIVATE I & II)</u>^{12,13}: (N = 601, MOTIVATE I; N = 475, MOTIVATE II) triple-class, treatment experienced patients with mean age of 45 years, 90% males, median CD4 cell count of 150-180 cells/mm³ and a mean HIV viral load of ~ 65,000 copies/mL.</p> <p><u>Results</u>: 24-week results showed significantly better virologic responses over 24 weeks with maraviroc-treated patients (45.6%-48.5% of twice-daily dosing arm patients achieved viral loads < 50 copies/mL) compared with placebo-treated patients (20.9%-24.6% of patients achieved viral loads < 50 copies/mL; <i>P</i> < 0.0001)</p>	<p>-Maraviroc should be considered for use in treatment-experienced patients who have only R5 virus and who are naive to CCR5 inhibitors.</p> <p>-Usual dose range: 150-600 mg bid</p>
Integrase Inhibitor	Raltegravir (Isentress®)	FDA-approved	<p><u>Phase III studies (BENCHMARK I & II)</u>^{4,5} (total N = 699) triple-class, treatment-experienced patients, failed current ARVs, with detectable viremia</p> <p><u>Results</u>: 24-week results showed significantly better virologic responses with raltegravir-treated patients (63% of patients achieved viral loads < 50 copies/mL) compared with placebo-treated patients (34% of patients achieved viral loads < 50 copies/mL) when added to OBT.</p>	<p>-Raltegravir should be considered for use in treatment-experienced patients who are naive to integrase inhibitors</p> <p>-Usual dose: 400 mg bid</p>
NNRTI	Etravirine (TMC-125)	FDA-approved	<p><u>Phase III studies (DUET I & II)</u>^{14,15} (N = 612 in DUET I; N = 591 in DUET II) triple-class, treatment-experienced patients with at least one NNRTI-associated resistance mutation and at least 3 primary PI mutations, failure of current ARV regimen. All patients received darunavir with low-dose ritonavir, along with investigator-selected NRTIs. Enfuvirtide was considered as an optional agent.</p> <p><u>Results</u>: 24-week results showed significantly better virologic patients (56%-62% of patients achieved viral loads < 50 copies/mL) compared with placebo-treated patients (39%-44% of patients achieved viral loads < 50 copies/mL; <i>P</i> = 0.005 in DUET I; <i>P</i> = 0.0003 in DUET II)</p>	<p>-Expanded access program available since July 2007</p> <p>-Usual dose: 200 mg bid with food</p>

^aThe entry inhibitors are a heterogeneous group that includes agents that act at several stages in the entry process. Maraviroc is a CCR5 antagonist

OBT-optimized background therapy (a regimen of active antiretroviral agents tailored to individual patients, selected by their physicians as most likely to be of benefit); ARV-Antiretroviral