Hope on the Horizon

For Patients With Resistance to All Commercially Available HIV Medications

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HIV Drug Pipeline – 2010

Agent	Class	Sponsor	Status
Rilpirivine, TMC 278	NNRTI	Tibotec	Phase III
~~Vicriviroc~~	~~CCR5 antagonist~~	~~Schering~~	~~Phase III~~
Elvitegravir	Integrase Inh.	Gilead	Phase III
Apricitabine, ATC*	NRTI	Avexa	Phase IIb
~~Berivimat*~~	~~Maturation Inh~~	~~Myriad~~	~~Phase IIb~~
UK453,061*	NNRTI	Pfizer	Phase II
IDX889*	NNRTI	Idenix/GSK	Phase II
GSK1349572*	Integrase Inh.	GSK/Shionogi	Phase IIb
GSK1265744*	Integrase Inh.	GSK/Shionogi	Phase IIa
PRO 140*	CCR5 antagonist	Progenics	Phase II
Ibalizumab*	CD4 antagonist	Taimed	Phase IIb
Gilead 9350	PK booster	Gilead	Phase II

*Potential activity against extensive drug resistance?

Courtesy of Bob Huff- TAG

- There is a small minority of patients with no remaining active agents due to resistance and/or tolerability . The total number of these patients in the U.S. is unknown. This population will likely increase in the future.

- Access to viable commercially available regimens may not be possible for these patients during the next 3 to 4 years.

- In a limited 2009 survey, 94 physicians from 47 cities reported a total of 252 of these patients. Note: Data mining can be performed from genotype/phenotype data bases to identify these patients.

- These patients are usually not allowed into HIV drug development clinical studies to protect them from functional monotherapy.

- Traditional single-drug expanded access programs (EAPs) or single patient TIND will not help these patients. Simultaneous access to several experimental drugs could be a solution.

- A new approach that removes barriers for a multi-drug EAP (MDEAP) in a centralized manner could help patients at risk of death before 2012, regardless of where they get care in the U.S.

- Three companies with HIV medications in phase II with potential activity to MDR-HIV have supported the idea. We are still waiting for dosing and phase 2b efficacy data to proceed with implementing an MDEAP (1-2 Q 2011).