

STRIVE

GlaxoSmithKline Protocol HPR20001: A Phase IIB, Randomized, Multicenter, Parallel Group Study to Evaluate the Short-Term Safety, Pharmacokinetics and Antiviral Activity of Four Blinded Dosing Regimens of GW640385/Ritonavir Therapy Compared to Open-label Current Protease Inhibitor Therapy in HIV-1 Infected Protease Inhibitor-Experienced Adults for 2 weeks with Long-Term Evaluation (> 48 weeks) of Safety, Pharmacokinetics and Antiviral Activity of Selected GW640385/Ritonavir Dosing Regimen(s) vs. a Ritonavir-boosted, Protease Inhibitor Containing Regimen.

Purpose: The main objective of this Phase IIb study is to choose a dose to progress into our Phase III program.

About the study: Subjects will participate in a screening period (up to Day-28 to Day-1; which may be extended to 32 days to ensure the availability of screening genotypic resistance testing), a randomized treatment phase (minimum of 48 weeks), a non-randomized treatment phase (that will last until either subjects no longer derive clinical benefit or commercial supplies of GW640385 become available), and a follow-up evaluation (performed 4 weeks after permanent discontinuation of investigational product(s)).

Required:

- Female subject must be of non-childbearing potential or must have a negative pregnancy test at screening and be practicing an effective method of birth control.
- Agreement for complete abstinence from intercourse from 2 weeks prior to administration of study drugs, throughout the study and for 2 weeks after discontinuation of all study medications. Should a female subject of childbearing potential decide to become sexually active during the course of the study, she must be counseled and be willing to use a contraception method, i.e. double barrier contraception (male condom/diaphragm).
- Plasma HIV1 RNA \geq 1,000 copies/mL at screening.
- Evidence of at least two or more multi-PI resistance mutations at screening or within three months prior to screening.
- Subjects currently receiving a regimen that has not changed for at least 8 weeks prior to screening and which contains a single RTV-boosted PI, excluding TPV/RTV (total daily dose of RTV must be \leq 200mg).

Not Allowed:

- Current history of thyroid abnormality which requires or has required treatment.
- History of clinically relevant pancreatitis or hepatitis within the previous 6 months of study drug administration.
- Significant blood loss (1 pint of whole blood) within 56 days of the screening visit of the study.
- Any acute laboratory abnormality at screening which, in the opinion of the investigator, should preclude the subject's participation in the study of an investigational compound.
- Treatment with other investigational drugs (IND)/therapies within 60 days prior to screening (Note: treatments available through a treatment IND or other expanded access mechanism will be evaluated on a case-by-case basis in consultation with the Sponsor).
- Subject has received an HIV-1 immunotherapeutic vaccine within 90 days prior to screening.
- Treatment with radiation or chemo therapy within 30 days of study drug administration or anticipated need for such treatment within the study.
- Treatment with certain medications (information provided during screening) within 30 days of commencement of study drug or an anticipated need during the study.

Study Location:

Orange County Center for Special Immunology
11190 Warner Ave Suite 411, Fountain Valley, CA 92708
Tel: 714-751-5800/Fax: 714-751-5860 Contact our Research Dept. at ext. 26