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Study No.: AZL30004
Title: A Phase IIIb/IV, Randomised, Open-Label, Multicentre Study to Evaluate the Efficacy, Safety and Tolerability of <i>TRIZIVIR</i> plus Efavirenz (Quad) Over 72 Weeks Versus Quad Therapy for 48 Weeks Followed by <i>TRIZIVIR</i> Alone for 24 Weeks Versus Quad Therapy for a minimum of 24 Weeks Followed by <i>TRIZIVIR</i> Alone for 48 Weeks in HIV - Infected Antiretroviral Therapy Naïve Adults.
Rationale: Using abacavir [ABC] 300mg lamivudine [3TC] 150mg , zidovudine [ZDV] 300mg in a fixed dose combination (TZV), plus Efavirenz (EFV) as a compact quadruple combination regimen in antiretroviral therapy (ART)-naïve subjects to achieve plasma human immunodeficiency virus (HIV)-1 ribonucleic acid (RNA) suppression was expected to optimise the induction phase, and allow for subsequent maintenance therapy with TZV alone without loss of antiviral potency. This study investigated the antiviral efficacy of TZV as part of both an induction and maintenance regimen, and also evaluated the best length of time for induction with a quadruple antiretroviral therapy in order to achieve a durable antiviral response with maximum tolerability.
Phase: IIIb/IV
Study Period: 5 November 2001 to 13 February 2004.
Study Design: A multicentre, randomised, open-label study.
Centres: 57 centres in 11 countries: Austria (4), Belgium (1), Estonia (1), France (16), Germany (6), Holland (1), Italy (12), Portugal (2), Spain (7), Sweden (2), and United Kingdom (5).
Indication: HIV-1 infection.
Treatment: At study entry (Day 1), all subjects began the following open-label quad regimen for a minimum of 24 weeks: TZV twice daily (BID) and Efavirenz [EFV] 600mg once daily (QD). After the 24-week Induction Phase, eligible subjects were randomised (1:1:1) to 1 of 3 open-label treatment regimens in the Maintenance Phase: 1. TZV BID plus EFV 600mg QD for 72 weeks (Quad 72). 2. TZV BID plus EFV 600mg QD for 48 weeks followed by TZV BID for 24 weeks (Quad 48/TZV 24). 3. TZV BID plus EFV 600mg QD for a minimum of 24 weeks followed by TZV BID for 48 weeks (Quad 24/TZV 48). Subjects who were eligible to enter the study extension were given open-label TZV for a further 96 weeks.
Objectives: The primary objective was to compare antiviral efficacy following 72 weeks of treatment with the following induction maintenance or quadruple therapy strategies in HIV-1-infected antiretroviral therapy naïve subjects: i. TZV BID plus EFV 600mg QD for 72 weeks, ii. TZV BID plus EFV 600mg QD for 48 weeks followed by TZV BID for 24 weeks, iii. TZV BID plus EFV 600mg QD for a minimum of 24 weeks followed by TZV BID for 48 weeks.
Primary Outcome/Efficacy Variable: The primary efficacy variable was the proportion of subjects with plasma HIV-1 RNA <50 copies/mL at Week 72 for the Intent-to-Treat (ITT) missing/switch = failure (M/S=F) population. M/S=F rate was number of subjects with a positive response, while still receiving study medication divided by number of subjects in the ITT population.
Secondary Outcome/Efficacy Variable(s): Secondary efficacy variables were: the proportion of subjects with plasma HIV-1 RNA <50 copies/mL at Week 24 for the All Subjects M/S=F population; time to plasma HIV-1 RNA <50 copies/mL (via Kaplan-Meier product-limit survival methods) for the Induction Phase only; the proportion of subjects with plasma HIV-1 RNA <50 copies/mL at Week 24 and Week 72 by Baseline plasma HIV-1 RNA strata; the proportion of subjects in the As-Treated population with plasma HIV-1 RNA <50 copies/mL at Week 72; time to treatment failure; time to virological failure; the average area under the plasma HIV-1 RNA curve minus Baseline (AAUCMB) at Week 24 and Week 72; the proportion of subjects with plasma HIV-1 RNA <5 copies/mL at Week 72 (presented in a separate report); immunological efficacy (CD4+ cell count) at Week 24 and Week 72. Changes in subject self-reported satisfaction with the quadruple and triple drug regimens over the course of the study was a health outcomes variable. The development of genotypic/phenotypic markers associated with reduced viral sensitivity to antiretroviral agents in subjects receiving study drug who failed to respond to treatment was a genotypic variable. Variables measured at Weeks 120 and 168 were not presented in the report.
Statistical Methods: The primary statistical objective of this study was to assess the proportion of subjects between treatment groups with plasma HIV-1 RNA levels < 50 copies/mL at Week 72. Calculation of the proportions was based on the ITT Randomised population using the M/S=F method. Comparisons were made using the confidence bound approach. Two-sided 95% confidence intervals (CIs) were calculated and non-inferiority of TZV+EFV (48 weeks) then TZV alone

(24 weeks) compared with TZV+EFV (72 weeks) was established if the 95% CI lay above –15%. If non-inferiority was established, the test was repeated for TZV+EFV (24 weeks) then TZV alone (48 weeks) compared with TZV+EFV (72 weeks). If the test for non-inferiority was significant then superiority was tested by comparison of the CI to zero and consideration of the 2-sided Cochran-Mantel-Haenszel test, with and without controlling for randomisation strata (Baseline Plasma HIV-1 RNA <100,000 copies/mL or ≥100,000 copies/mL). Time-to-event analyses in the Induction Phase used Kaplan-Meier product-limit survival estimates; median time and 95% CIs were calculated. Time-to-event analyses in the Maintenance Phase compared treatment groups via a log-rank test controlling for randomisation strata. In the case of strong evidence for non-proportional hazards, the treatment groups were compared via the Wilcoxon test controlling for randomisation strata. Treatment difference in mean AAUCMB in log₁₀ plasma HIV-1 RNA over 72 weeks was presented with 95% CIs calculated using analysis of variance (ANOVA) or Hodges Lehmann estimators, depending on Normality. Absolute changes from Baseline in CD4+ cell counts were compared at Week 72 between treatment groups using the Wilcoxon Rank Sum test.

The ITT (All Subjects) population consisted of all subjects who met the inclusion/exclusion criteria. If <5% of subjects had no documented evidence of receiving at least 1 dose of study drug, the population could be replaced with the ITT Exposed (E) (All Subjects) population. The ITT (Randomised) population consisted of all subjects who were randomised after the Week 24 visit. If <5% of subjects had no documented evidence of receiving at least 1 dose of randomised study drug, the population could be replaced with the ITT:E (Randomised) population. The As Treated population excluded subjects who were randomised but did not take randomised treatment, who had no post-Week 24 data or who had major protocol deviations. The Health Outcomes population consisted of all subjects who completed the HIV Treatment Satisfaction Questionnaire (TSQ) for at least 1 visit while receiving study drug as indicated by protocol and randomisation. Safety analyses in the Induction Phase were conducted on all subjects enrolled into the study with documented evidence of having received at least 1 dose of study drug. Safety analyses in the Maintenance Phase were conducted on all subjects randomised into the study with documented evidence of having received at least 1 dose of randomised treatment. The Virology population consisted of all subjects who had at least 1 phenotypic or 1 genotypic assessment available.

Study Population:

Male or non-pregnant, non-lactating female subjects using adequate contraception were eligible if they were aged ≥16 years (or ≥18 years in some countries according to local regulatory requirements), were HIV-1-infected; were naïve to ART or had <2 weeks of prior therapy with any licensed or investigational protease inhibitor [PI], nucleoside reverse transcriptase inhibitor [NRTI] or nucleotide RTI and were naïve to non-NRTIs. There was no plasma HIV-1 RNA or CD4+ cell count cut-off for entry into this study. Subjects were stratified based on their Baseline plasma HIV-1 RNA as <100,000 copies/mL or ≥100,000 copies/mL. Subjects were excluded if they: were unlikely to be able to complete the dosing period of 72 weeks in the investigator’s opinion; had current alcohol or illicit drug use which, in the opinion of the investigator, could have interfered with the subject’s ability to comply with the dosing schedule and protocol evaluations; had a malabsorption syndrome or other gastrointestinal dysfunction which might have interfered with drug absorption or rendered the subject unable to take oral medication; had a history of clinically relevant pancreatitis or hepatitis within 6 months prior to screening, or signs and symptoms of liver cirrhosis; had any of the following laboratory results within 14 days prior to the first dose of study medication: haemoglobin concentration <10.0g/dL (6.3mmol/L) for men and <9.0g/dL (5.7mmol/L) for women, absolute neutrophil count <1,000 cells/mm³ (<1.00GI/L), platelet count <75,000 cells/mm³ (<75GI/L), aspartate transaminase or alanine transaminase >5 times the upper limit of normal (ULN), total bilirubin >2 mg/dL (>34µmol/L), albumin <3 g/dL (<30g/L), serum pancreatic amylase >1.5 times the ULN, estimated creatinine clearance <40mL/min; had participated in an investigational HIV vaccine trial and received a dose of vaccine within the past 3 months or had received gene therapy prior to study drug administration; had any serious medical condition, such as diabetes, congestive heart failure, cardiomyopathy or other cardiac dysfunction, which in the opinion of the investigator could have compromised the safety of the subject; had an active acquired immune deficiency syndrome (AIDS)-defining opportunistic infection or disease according to the 1993 Centre for Disease Control and Prevention AIDS surveillance definition (Clinical Category C) (excluding CD4+ counts less than 200 cells/mm³); were receiving other investigational treatments (exception – treatments available through a Treatment Investigational New Drug or other expanded access mechanism were evaluated individually in consultation with the Sponsor); had required treatment with radiation therapy or cytotoxic chemotherapeutic agents within 4 weeks prior to entry, or had an anticipated need for these agents within the study period; had required treatment with immunomodulating agents, (such as systemic corticosteroids, interleukins, vaccines, or interferons) or any agent with documented activity against HIV-1 *in vitro* (e.g. hydroxyurea or foscarnet) within 4 weeks prior to study entry; were prescribed/taking astemizole, cisapride, midazolam, terfenadine, triazolam, ergot derivatives or products containing St. John’s Wort (*Hypericum Perforatum*) within 28 days; or had a history of allergy to any of the study drugs or any excipients therein.

	Induction	Maintenance
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	TZV+EFV	Quad 72	Quad 48/ TZV 24	Quad 24/ TZV 48
Number of Subjects:				
Planned, N	334			
Enrolled/randomised, N	381	81	83	82
Completed, n (%)	230 (60)	59 (73)	70 (84)	71 (87)
Total Number Subjects Withdrawn, n (%)	151 (40)	22 (27)	13 (16)	11 (13)
Withdrawn from TZV due to Adverse Events, n (%)	73 (19)	2 (2)	0	0
Withdrawn from TZV due to Lack of Efficacy, n (%)	22 (6)	2 (2)	2 (2)	1 (1)
Withdrawn for Other Reasons, n (%)	56 (15)	18 (22)	11 (13)	10 (12)
Demographics				
N (ITT:E [All Subjects]/ITT:E [Randomised])	377	80	83	82
Females: Males	104: 273	24: 56	19: 64	18: 64
Mean Age, years (standard deviation [SD])	37.0 (9.91)	38.1 (11.11)	37.4 (9.06)	37.3 (10.38)
White, n (%)	255 (68)	51 (64)	55 (66)	58 (71)
Primary Efficacy Results: (ITT:E, M/S=F population)				
Subjects with plasma HIV-1 RNA <50 copies/mL at Week 72:		Maintenance		
		Quad 72 (N=80)	Quad 48/ TZV 24 (N=83)	Quad 24/ TZV 48 (N=82)
Subjects with HIV-1 RNA <50 copies/mL, n (%)		60 (75)	63 (76)	61 (74)
Treatment difference, Quad 72 vs other regimen, %		NA	-1	1
95% CI		NA	-14, 12	-13, 14
p-value		Not reported	Not reported	Not reported
NA Not applicable.				
Secondary Outcome Variable(s): (ITT:E, M/S=F Population)				
				Induction TZV+EFV (N=377)
Subjects with plasma HIV-1 RNA <50 copies/mL at Week 24:				
Subjects with HIV-1 RNA <50 copies/mL, n (%)				241 (64)
Time to plasma HIV-1 RNA <50 copies/mL (days):				
Median time				85.0
95% CI				84.0, 87.0
		Induction TZV+EFV (N=377)	Maintenance Quad 72 (N=80)	Quad 48/ TZV 24 (N=83)
			Quad 24/ TZV 48 (N=82)	
Subjects with plasma HIV-1 RNA <50 copies/mL by Baseline plasma HIV-1 RNA strata:				
Baseline <100,000 copies/mL, N	194	41	44	45
Week 24 with HIV-1 RNA <50 copies/mL, n (%)	126 (65)	39 (95)	42 (95)	44 (98)
Week 72 with HIV-1 RNA <50 copies/mL, n (%)	NA	30 (73)	38 (86)	36 (80)
Baseline ≥100,000 copies/mL, N	183	39	39	37
Week 24 with HIV-1 RNA <50 copies/mL, n (%)	115 (63)	38 (97)	37 (95)	37 (100)
Week 72 with HIV-1 RNA <50 copies/mL, n (%)	NA	30 (77)	25 (64)	25 (68)
Subjects with plasma HIV-1 RNA <50 copies/mL at Week 72 (As Treated population):				
N		60	66	68
Subjects with HIV-1 RNA <50 copies/mL, n (%)		59 (98)	61 (92)	59 (87)
Treatment difference, Quad 72 vs other regimen, %		NA	6	12
95% CI		NA	-1, 13	3, 20
Time to treatment failure (days):				
Median, 95% CI		NC	NC	NC
				544.0 (538.0, NC)
Time to virological failure (days):				
Median, 95% CI		NC	NC	NC

NC Not calculable because <50% of subjects failed.				
AAUCMB for plasma HIV-1 RNA at Week 24 and Week 72 (log₁₀ copies/mL):				
Week 24, mean (SD)	-2.446 (0.9220)	NA	NA	NA
Week 72, mean (SD)	NA	-3.108 (0.6672)	-3.045 (0.6544)	-3.026 (0.6710)
Immunological efficacy (CD4+ cell count, cells/mm³)				
Week 24				
AAUCMB, mean (SD)	74.6 (75.59)	NA	NA	NA
Change from Baseline to Week 24, mean (SD)	115.3 (99.96)	NA	NA	NA
Week 72				
AAUCMB, mean (SD)	NA	126.5 (91.16)	150.7 (69.91)	141.6 (106.59)
Change from Baseline to Week 24, mean (SD)	NA	172.7 (119.99)	226.2 (141.81)	206.8 (165.52)
Health Outcomes variables: (Health Outcomes population)				
	Induction	Maintenance		
	TZV+EFV	Quad 72	Quad 48/ TZV 24	Quad 24/ TZV 48
	(N=296)	(N=75)	(N=75)	(N=71)
Total satisfaction score on HIV TSQ (scale of 0-100)				
Week 4, mean (SD) ^a	78.0 (17.37)	77.9 (17.19)	82.0 (13.55)	81.4 (13.24)
Change from Week 4, mean (SD) ^a				
Week 12	5.1 (11.67)	6.8 (10.41)	1.5 (8.85)	5.4 (12.90)
Week 24	5.4 (15.06)	6.9 (15.28)	3.7 (13.06)	4.5 (15.18)
Week 36	NA	8.4 (13.47)	2.6 (12.19)	7.5 (13.48)
Week 48	NA	7.1 (15.64)	4.0 (12.82)	7.2 (14.28)
Week 60	NA	4.9 (12.89)	6.2 (13.34)	9.7 (13.52)
Week 72	NA	6.2 (12.83)	6.8 (13.67)	8.8 (13.85)
a Based on number of subjects with evaluable data.				
NA Not applicable.				
Genotypic/phenotypic variables: (Virology population)				
In the few subjects experiencing virologic failure during the Maintenance Phase (2/82 in the Quad 24/TZV 48 group, 7/83 in the Quad 48/TZV 24 group, and 9/80 in the Quad 72 group), most genotypes remained 'wild-type' on virological failure, with infrequent mutation/mixtures at residue 184 and the expected and corresponding reduction in susceptibility to 3TC. Phenotypes were in the main predictable from genotype results. Cross-resistance with non-study NRTI was not observed apart from 2 instances of borderline resistance to didanosine (ddl) in 2 subjects with detectable M184V or M184I, both in the Quad 24/TZV 48 group.				
Safety Results: (ITT Population) - Adverse events (AEs) and serious adverse events (SAEs) were collected at every study visit starting after the first dose of investigational product on Day 1 until the follow-up evaluation at least 28 days after permanent discontinuation of all study drugs. On-therapy AEs in the Induction Phase had an onset date on or after the first dose data of TZV/EFV but prior to Week 26, or an onset before the first dose date of TZV/EFV but worsened before Week 26. On-therapy AEs in the Maintenance Phase had an onset date on or after Week 26, or an onset prior to Week 26 but worsened during the randomised phase.				
	Induction	Maintenance		
	TZV+EFV	Quad 72	Quad 48/ TZV 24	Quad 24/ TZV 48
	(N=377)	(N=80)	(N=84)	(N=81)
Most Frequent Adverse Events – On-Therapy	n (%)	n (%)	n (%)	n (%)
Subjects with any AE(s), n (%)	327 (87)	60 (75)	54 (64)	54 (67)
Headache	39 (10)	2 (3)	6 (7)	6 (7)
Cough	20 (5)	4 (5)	5 (6)	6 (7)
Pharyngolaryngeal pain	10 (3)	1 (1)	5 (6)	4 (5)
Nausea	112 (30)	3 (4)	2 (2)	4 (5)
Upper respiratory tract infection	2 (<1)	0	5 (6)	3 (4)
Diarrhoea	44 (12)	5 (6)	4 (5)	3 (4)

Herpes simplex	17 (5)	3 (4)	3 (4)	3 (4)
Eczema	10 (3)	1 (1)	0	3 (4)
Fatigue	56 (15)	1 (1)	1 (1)	2 (2)
Influenza-like illness	8 (2)	5 (6)	6 (7)	1 (1)
Insomnia	53 (14)	4 (5)	3 (4)	1 (1)
Arthralgia	8 (2)	4 (5)	3 (4)	1 (1)
Vomiting	51 (14)	5 (6)	1 (1)	1 (1)
Influenza	7 (2)	4 (5)	1 (1)	1 (1)
Depression	32 (8)	7 (9)	0	1 (1)
Dizziness	68 (18)	0	2 (2)	0
Serious Adverse Events - On-Therapy				
n (%) [n considered by the investigator to be related to study medication]				
	Induction	Maintenance		
	TZV+EFV	Quad 72	Quad 48/ TZV 24	Quad 24/ TZV 48
	(N=377)	(N=80)	(N=84)	(N=81)
Subjects with any SAEs, n (%)	67 (18)	6 (8)	4 (5)	7 (9)
	n (%) [related]			
Abdominal pain	0	1 (1) [0]	0	1 (1) [0]
Condyloma acuminatum	1 (<1) [0]	0	0	1 (1) [0]
Urinary tract infection	1 (<1) [0]	0	0	1 (1) [0]
Gangrene	0	0	0	1 (1) [0]
Mental disorder	0	0	0	1 (1) [0]
Pancreatitis	0	0	0	1 (1) [0]
Pneumonia streptococcal	0	0	0	1 (1) [0]
Pneumothorax	0	0	0	1 (1) [0]
Suicide attempt	0	0	0	1 (1) [0]
Asthma	0	1 (1) [0]	1 (1) [0]	0
Bladder neoplasm	0	0	1 (1) [0]	0
Headache	0	0	1 (1) [0]	0
Nephrolithiasis	0	0	1 (1) [0]	0
Upper respiratory tract infection	0	0	1 (1) [0]	0
Abortion spontaneous	0	2 (3) [1]	0	0
Diarrhoea	1 (<1) [1]	1 (1) [0]	0	0
Ischaemic stroke	0	1 (1) [0]	0	0
Myocardial infarction	0	1 (1) [0]	0	0
Drug hypersensitivity	29 (8) [28]	0	0	0
Hypersensitivity	5 (1) [5]	0	0	0
Gastroenteritis	3 (<1) [0]	0	0	0
Anaemia	2 (<1) [2]	0	0	0
Depression	2 (<1) [2]	0	0	0
Neutropenia	2 (<1) [2]	0	0	0
Sepsis	2 (<1) [0]	0	0	0
Agitation	1 (<1) [1]	0	0	0
Anal fissure	1 (<1) [0]	0	0	0
Appendicitis	1 (<1) [0]	0	0	0
Cachexia	1 (<1) [0]	0	0	0
Cerebral toxoplasmosis	1 (<1) [0]	0	0	0
Colitis herpes	1 (<1) [0]	0	0	0
Cough	1 (<1) [0]	0	0	0
Dermatosis	1 (<1) [1]	0	0	0
Dyspnoea	1 (<1) [0]	0	0	0
Fibroadenoma of breast	1 (<1) [0]	0	0	0
Gastritis	1 (<1) [0]	0	0	0
Gastroenteritis clostridial	1 (<1) [0]	0	0	0

Gastroenteritis cryptosporidial	1 (<1) [0]	0	0	0
Giardiasis	1 (<1) [0]	0	0	0
Granulocytopenia	1 (<1) [1]	0	0	0
Herpes ophthalmic	1 (<1) [0]	0	0	0
Herpes zoster	1 (<1) [0]	0	0	0
Hypertonia	1 (<1) [0]	0	0	0
Leishmaniasis	1 (<1) [0]	0	0	0
Nausea	1 (<1) [1]	0	0	0
Neutrophil count decreased	1 (<1) [1]	0	0	0
Non-Hodgkin's lymphoma	1 (<1) [0]	0	0	0
Pancreatitis acute	1 (<1) [1]	0	0	0
Pleurisy	1 (<1) [0]	0	0	0
Pneumonia	1 (<1) [0]	0	0	0
Pneumonia pneumococcal	1 (<1) [0]	0	0	0
Pulmonary embolism	1 (<1) [0]	0	0	0
Pyrexia	1 (<1) [0]	0	0	0
Ranula	1 (<1) [0]	0	0	0
Retinal detachment	1 (<1) [0]	0	0	0
Rhabdomyolysis	1 (<1) [0]	0	0	0
Salpingitis	1 (<1) [0]	0	0	0
Thrombosis	1 (<1) [0]	0	0	0
Tubo-ovarian abscess	1 (<1) [0]	0	0	0
Vasculitis cerebral	1 (<1) [0]	0	0	0
Vision blurred	1 (<1) [0]	0	0	0
Vomiting	1 (<1) [1]	0	0	0
Weight decreased	1 (<1) [0]	0	0	0
White blood cell count decreased	1 (<1) [1]	0	0	0
Subjects with fatal SAEs, n (%)	1 (<1)	1 (1)	0	0
	n (%) [related]			
Pulmonary embolism	1 (<1) [0]	0	0	0
Anaemia	0	1 (1) [0]	0	0

Conclusion:

The analysis of the primary variable demonstrated the non-inferiority of a TZV maintenance regimen relative to continuing therapy with a TZV/EFV quadruple regimen. In the ITT analysis, the proportions of subjects with <50 copies/mL plasma HIV-1 RNA at Week 72 were comparable across groups, and non-inferiority of TZV maintenance therapy compared to TZV+EFV was established. During the Induction Phase, AEs were reported by 327 (87%) subjects and the most commonly reported AEs were nausea and dizziness. During the Maintenance Phase, AEs were reported by 60 (75%) subjects in the Quad 72 group, 54 (64%) subjects in the Quad 48/TZV 24 group, and 54 (67%) subjects in the Quad 24/TZV 48 group. The most commonly reported AEs were depression in the Quad 72 group, headache and influenza-like illness in the Quad 48/TZV 24 group, and headache and cough in the Quad 24/TZV 48 group. In the Induction Phase, SAEs were reported by 67 (18%) subjects and the most commonly reported SAE was drug hypersensitivity. In the Maintenance Phase, SAEs were reported by 6 (8%) subjects in the Quad 72 group, 4 (5%) subjects in the Quad 48/TZV 24 group, and 7 (9%) subjects in the Quad 24/TZV 48 group. The only SAE reported by more than 1 subject in a treatment group was spontaneous abortion (2 subjects in the Quad 72 group). One subject had a fatal SAE of pulmonary embolism during the Induction Phase and 1 subject had a fatal SAE of anaemia during Quad 72 maintenance therapy.

Publications:

Randomised comparison of maintenance therapy with trizivir [TZV] + efavirenz [EFV] vs TZV in naive HIV-1 infected subjects: TIME study De Wit, S.; Johnson, M.; Gazzard, B.; Bergmann, J. F.; Reynes, J.; Estrada, V.; Castagna, A., and Rockstroh, J., 7th International Congress on Drug Therapy in HIV Infection; Glasgow; Scotland. 2004 Nov 14

INDUCTION THERAPY WITH TRIZIVIR (ZIDOVUDINE/LAMIVU- DINEIABACAVIR) [TZV] PLUS EFAVIRENZ [EFV]: TIME STUDY (AZI-30004) RESULTS AT 24 WEEKS Johnson M., De Wit S. Gazzard B. Bergmann JI. Reynes J. Estrada V. Castagna A. Rockstroh J., 9th European AIDS Conference (EACS) 1st EACS Resistance and

Pharmacology Workshop; Warsaw; Poland. 2003 Oct 25

Efficacy and safety of AZT/3TC/ZDV (Trizivir) maintenance treatment after first line quadruple induction therapy- interim 24 weeks: data from AZLF3004/TRISUD Jean-Marie Ragnaud', Benedicte Delmas Herve Gallais' Dominique Peyramond' Henri Laurichesse Pierre Dellamonica jean-Luc PL-Ilegrid ThierryAllegre NathalieAudebert' JacquesReyn on behalf of InfectioSud group, 6th International Congress on Drug Therapy in HIV Infection; Glasgow; Scotland. 2002 Nov 17

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