

2nd International Conference on Hematology & Blood Disorders

September 29-October 01, 2014 DoubleTree by Hilton Baltimore-BWI Airport, USA

ENESTgoal: Evaluation of Treatment-Free Remission (TFR) in patients with Chronic Myeloid Leukemia in Chronic Phase (CML-CP) and sustained deep Molecular Response (MR) following switch to nilotinib

Andrea Magley⁴, Eric J Feldman¹, Michael W Deininger², Jerald Radich³, Christopher Keir⁴, Felice Lin⁴ and Michael Mauro⁵

¹Weill Cornell Medical College, USA

²University of Utah, USA

³Fred Hutchinson Cancer Research Center, USA

⁴Novartis Pharmaceuticals Corporation, USA

⁵Memorial Sloan Kettering Cancer Center, USA

Sustained TFR has been reported in clinical trials of patients with CML-CP who achieved sustained deep MR on imatinib therapy. Nilotinib treatment results in high rates of sustained deep MR, a key eligibility criterion for TFR studies. The randomized, phase 2 ENESTgoal study (NCT01744665) will evaluate TFR among patients with CML-CP who achieve sustained MR4.5 (BCR-ABL $\leq 0.0032\%$ on the International Scale [IS] by real-time quantitative polymerase chain reaction [RQ-PCR]) after switching to nilotinib. ENESTgoal will enroll approximately 300 patients with major molecular response (BCR-ABL IS $\leq 0.1\%$) but with detectable disease (BCR-ABL IS $> 0.0032\%$), as assessed by a central laboratory, after ≥ 1 year of imatinib therapy. Patients will switch to nilotinib 300 mg twice daily on study entry and be monitored quarterly for up to 2 years; those who achieve confirmed MR4.5 during the monitoring phase will be randomized to enter a 1- or 2-year consolidation phase of continued nilotinib treatment. Patients will then stop nilotinib therapy and enter the 3-year TFR phase if MR4.5 is maintained throughout the consolidation phase. RQ-PCR assessments will be performed monthly for the first 6 months of the TFR phase, then every 2 months for 18 months and then quarterly thereafter. Patients with molecular relapse, defined in ENESTgoal as confirmed loss of MR4 (or BCR-ABL IS $> 0.01\%$), will re-initiate nilotinib therapy. The primary endpoint of the study is the molecular relapse-free rate at 6 months after suspension of nilotinib therapy. ENESTgoal is currently open for enrollment in the United States.

ejf2001@med.cornell.edu