the remainder of the trial. Blood levels of AZA metabolites 6-thiouanine and 6-methylmercaptopurine were measured biweekly. After receiving 2 weeks of AZA, patients were started on pegloticase (8 mg IV) and were treated biweekly for 24 weeks. The primary endpoint was the persistent lowering of serum urate to <6 mg/dL at the last three consecutive study visits. Patients who had an increase in serum urate to >6 mg/dL while on therapy did not receive additional pegloticase. All patients received infusion prophylaxis with hydrocortisone as well as gout flare prophylaxis.

Results: To date, 12 patients have been enrolled. All patients were male, 75% white and 25% African American. Mean age was 62.4 ± 14.7 years, the mean BMI was 31.1 ± 4.5 and the mean duration of gout was 13.8 ± 9.2 years. At baseline, all patients had visible tophi; 58.3% suffered from gout flares; 81.8% had hypertension; 45.5% had dyslipidemia and 9.0% had coronary artery disease. Of the 12 patients, 6 have completed the full course of treatment with persistent urate lowering and 2 remain on treatment also with persistent urate lowering (figure). 2 patients lost the urate lowering effect, both after 2 doses of pegloticase, and did not receive additional therapy. 1 patient experienced an infusion reaction during the first dose (1 infusion reaction in 90 infusions [1.1%] in the entire trial to date) and 1 subject had subjective symptoms of AZA intolerance with no laboratory abnormalities; these subjects discontinued the study and were not evaluable for the endpoint. No adverse events related to AZA were reported and gout flares were noted in 6 subjects (mean 1.5 flares/patient with flares). Conclusion: AZA can be used safely in subjects with chronic refractory gout and appears to increase the frequency of subjects experiencing long term lowering of serum urate.

References: