

FDA clinical review team has identified following additional adverse events that are relation to administration of Panzyga. These are outlined below:

Subject ID	Adverse Event	Date of 1 st infusion of Panzyga	Date of occurrence	Attribution-applicant	Attribution - FDA	Reason
(b) (6)	Headache	(b) (6)	3/22/2012	Unlikely related	Related	Headache occurred within 24 hours of second infusion of Panzyga and preceded fever. No alternative explanation for headache.
	Headache		4/4/2012	Not related	Related	Headache occurred within 10 hours of starting the first infusion of Panzyga.
	Anemia		3/19/2012	Not related	Related	This subject dropped hemoglobin from 12.3gm/dl to 9.3gm/dl on (b) (6) along with conversion from *DAT negative to positive on day #3 of the study.
	Anemia		8/27/2012	Unlikely	Related	This subject dropped hemoglobin from 12.1 gm/dl down to 8.6 gm/dl on (b) (6) in setting of conversion to DAT positivity.
	Abdominal pain Urticaria		7/5/2012	Not related	Related	This subject developed infusional reaction on day #1. Day#2 was not administered. Abdominal pain and urticaria occurred within 48 hrs. after first dose of Panzyga.
	Headache Dizziness Asthenia Nausea		6/29/2012	Unlikely related	Related	This subject developed these symptoms within 72 hours of receiving Panzyga. In the absence of any additional explanation of these symptoms, these are attributed to IVIG product.

- *DAT Direct anti-globulin test