

2nd Preclinical Study

The pig study was conducted at University of Rzeszów in 2014. It provides some very important safety and toxicology data which is summarized as follows:

- Pigs were raised to 150 lbs each. Because their digestive tract is similar to humans, this study closely simulates actual human dosage and treatment.
- All pigs received both IV and Oral dosing simultaneously, with no negative side effects. The pigs were healthy with no cancer -- this is very significant because there was no cancer to absorb any 3BP, thus tissue concentrations were likely higher.
- Escalation dosage was similar to humans, with 5 days on and 2 days off, simulating an actual treatment protocol, with no demonstrated cytotoxicity.
- Regular blood profiles were drawn, and all blood chemistry, blood metabolic panels, and internal organ tissue pathology was completely normal in all subjects.

The study design was as follows:

- 2 sets of pigs dosed with KAT: 1 IV and 1 oral.
- 4 groups of pigs in each set: 1 mg/kg, 2.5 mg/kg, 5 mg/kg, and control group.
- 3 pigs per group. ~70kg per pig.
- Pigs were dosed 5 days on/2 days off for 5 weeks. Blood sampling done several times per day. Blood chemistry and blood counts tested.
- No toxicities reported.