

Title: An Open Label, Prospective, Pharmacokinetic/ Pharmacodynamic and Safety Evaluation of Intravenous Oseltamivir (Tamiflu®) in the Treatment of Children 1 to 12 Years of Age with Influenza Infection (NP25139B)

IRB# 2010-040

Principal Investigator: Ann Petru, MD

Synopsis:

This study is a prospective, open label, pharmacokinetic/ pharmacodynamic and safety evaluation of IV oseltamivir therapy in three cohorts of children with influenza infection aged:

- 6-12 years (Cohort I)
- 3-5 years (Cohort II)
- 1-2 years (Cohort III)

Children with symptoms of influenza will be considered for enrollment into this study. The onset of symptoms should be less than 48 hours prior to the first dose of oseltamivir. However, patients with influenza symptoms for up to 96 hours prior to first dose will be allowed into the study.

Once eligibility is confirmed, patients will be enrolled into the age appropriate cohort. Enrollment into cohorts will occur in parallel. The parent/guardian must agree to the child receiving intravenous oseltamivir. Patients may receive a full course of therapy (10 doses) intravenously, or, at the discretion of the investigator, may switch to oral dosing with oseltamivir once intravenous therapy is no longer medically necessary. If medically necessary, patients may receive up to an additional 10 doses of IV or oral oseltamivir at the discretion of the investigator following the 10 initial doses. Follow-up visits will occur on Days 15 and 30.

Objectives:

- To define the pharmacokinetics of oseltamivir and oseltamivir carboxylate and evaluate the safety profile following intravenous (IV) administration of oseltamivir phosphate in children between 1 and 12 years of age with influenza.
- To evaluate the viral load and viral shedding
- To evaluate all isolates for phenotypic and, where necessary, genotypic resistance

Length of Study:

Up to approximately 4 weeks (from screening through to study completion) for each enrolled patient as follows:

- Screening: Up to 4 days (96 hours)
- Dosing: 5 days (10 doses)
- Additional dosing (if clinically indicated): up to 5 additional days (10 doses)
- Follow-up: approximately 30 days after first administration of study medication