**Background**

- Influenza remains a significant cause of morbidity and mortality globally.
- Peramivir (PVR) is a potent neuraminidase inhibitor with in vitro activity against all influenza virus subtypes.
- Previous studies demonstrated the efficacy and safety of PVR as a single dose intravenous (IV) treatment for acute uncomplicated influenza and has been FDA-approved for patients 2 years and older who have been symptomatic for no more than two days under the trade name of Rejuvancy®.
- A single arm study previously demonstrated the safety and effectiveness of IV peramivir in a pediatric influenza population in Japan.
- We conducted an open label study to evaluate the safety and effectiveness of a single dose administration of IV peramivir versus oral oseltamivir for 5 days in a US population of pediatric subjects with acute uncomplicated influenza (BCX1812-305, NCT02369159).
- Interim results are reported.

**Methods**

- Phase 3, open-label, randomized active control trial, initiated February 2015
- Eligible subjects: Male/ female, age 0-<18 years
- Acute uncomplicated influenza symptom onset within 48 hours at Screening:
  - Fever: Oral ≥100°F Rectal ≥101.3°F and ≥ 1 respiratory symptom (cough/ rhinitis) or
  - Positive rapid antigen test
- Parent/ guardian written informed consent plus assent by subjects ≥ 7 years

**Demographics**

- **122 subjects enrolled up to a data cutoff of March 31, 2017**

**Treatment randomization (4:1: PVR: OSE) > 28 days stratified by age cohort:**

- Birth cohort
  - Age: 0-11 months
  - Sample Size: 30
  - Peramivir: 23 (77%)
  - Oseltamivir: 7 (23%)

- Age: > 2 years
  - Sample Size: 122
  - Peramivir: 99 (80%)
  - Oseltamivir: 23 (18%)

**Outcome measures:**

- Safe: Adverse Events (AEs) and laboratory assessments
- Pharmacokinetics (PK): PVR plasma concentrations up to 6 hrs post dose
- Viral shedding were generally similar to those observed in adults.

**Peramivir PK**

- Age cohort
  - Number of subjects: n = 99
  - Median (95% CI)
    - Geom. mean (mg/L)
      - A/H3N2: 73.4 (70.0, 77.0)
      - A/H1N1: 22.3 (19.8, 24.9)
      - B: 25.1 (22.2, 28.1)
    - AUC(0-3 h) (ng.h/mL)
      - A/H3N2: 113.2 (88.4, 130.4)
      - A/H1N1: 102.8 (87.5, 120.0)
      - B: 103.4 (89.9, 118.4)

**Results**

**Safety (Treated population)**

- Category: n (%) =
  - Number of subjects with any Serious AE 0 (0%)
  - Number of subjects with AE leading to study drug discontinuation 0 (0%)
  - Treatment-emergent AEs Possibly, Probably or Definitely Related to Study Drug 8 (9%)
  - Clinical significance changes in clinical chemistry, hematology or urinalysis 2 (2%)
  - Treatment-emergent AEs occurring in ≥ 2 subjects overall
    - Vomiting 3 (3%)
    - Nausea 3 (3%)
    - Pyrexia 2 (2%)
    - Tympanic membrane hyperaemia 0 (0%)
    - AST increase 2 (2%)
    - ALT increase 2 (2%)

**Effectiveness outcomes**

- Proportion of ITT population with positive virological titer, n (%) =
  - Baseline: 63/63 (100%), 31/50 (62%), 10/29 (34%)
  - Day 3: 14/14 (100%), 10/13 (77%), 0/5 (0%)
  - Day 7: 6/6 (100%), 0/0 (0%), 0/1 (100%)
  - Day 14: 5/5 (100%), 0/0 (0%), 0/1 (100%)

**Conclusions**

- Single dose IV peramivir was generally safe and well tolerated in pediatric subjects with acute uncomplicated influenza.
- Peramivir exposure (Cmax and AUC) in children 2-18 years old was consistent with adult exposure.
- Time to alleviation of influenza symptoms and reduction in virus shedding were generally similar to those observed in adults.
- The study is continuing to enroll additional subjects below the age of 2 years.

**References**


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