Carnexiv™ (carbamazepine) – New Orphan Drug Approval

- On October 7, 2016, Lundbeck announced the FDA approval of Carnexiv (carbamazepine) injection as replacement therapy for oral carbamazepine formulations, when oral administration is temporarily not feasible, in adults with the following seizure types:
  - Partial seizures with complex symptomatology
  - Generalized tonic-clonic seizures
  - Mixed seizure patterns which include the above, or other partial or generalized seizures
- Carnexiv is not indicated for the treatment of absence seizures (including atypical absence). Carbamazepine has been associated with increased frequency of generalized convulsions in these patients.
- The efficacy of Carnexiv is based upon bioavailability studies comparing oral carbamazepine to Carnexiv. The pharmacokinetics of the principal metabolite of carbamazepine were similar following both intravenous and oral dosing.
- Similar to the oral formulations of carbamazepine, Carnexiv carries a boxed warning for serious dermatologic reactions and aplastic anemia and agranulocytosis.
- Other warnings and precautions of Carnexiv include impairment of renal function, drug reaction with eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity, suicidal behavior and ideation, embryofetal toxicity, abrupt discontinuation and seizure risk, hyponatremia, potential impairment of neurologic function, hepatic toxicity, increased intraocular pressure, and hepatic porphyria.
- The most common adverse reactions (≥ 2%) with Carnexiv use were dizziness, somnolence, blurred vision, diplopia, headache, infusion-related reaction, infusion site pain, and anemia.
- The total daily dose of Carnexiv is 70% of the total daily oral carbamazepine dose from which patients are being switched. The total daily dose of Carnexiv should be equally divided into four 30-minute intravenous infusions separated by 6 hours.
  - Patients should be switched back to oral carbamazepine administration at their previous total daily oral dose and frequency of administration as soon as clinically appropriate.
  - The use of Carnexiv for more than 7 days has not been studied and is not recommended.
- Lundbeck plans to launch Carnexiv in early 2017 as 200 mg/20mL (10 mg/mL) single dose vials.