

Abstract for Epilepsy Pipeline Review

King Pharmaceuticals® Inc., headquartered in Bristol, Tennessee, is a vertically integrated branded pharmaceutical company. King, an S&P 500 Index company, seeks to capitalize on opportunities in the pharmaceutical industry through the development, including through in-licensing arrangements and acquisitions, of novel branded prescription pharmaceutical products and technologies that complement the Company's focus in specialty-driven markets, particularly neuroscience and hospital. King's wholly owned subsidiary, Alpharma Inc., is also a leader in the development, registration, manufacture, and marketing of pharmaceutical products for food-producing animals.

Vanquix™ (diazepam) Auto-Injector is a device undergoing Phase III clinical development. It is based on the diazepam auto-injector that has been in use since 1991 in the United States Army. The Army's device was restricted to 10 mg diazepam, but Vanquix is available in doses of 5, 10, and 15 mg. In addition, the Vanquix Auto-Injector has been redesigned to be safer and more user-friendly, since it is meant for use by caregivers who are not healthcare professionals.

The Vanquix Auto-Injector is being developed for the management of patients with epilepsy who experience episodes of increased seizure activity, referred to as serial seizures, sequential seizures, cluster seizures, crescendo seizures, but most often as acute repetitive seizures (ARS). Patients with ARS can progress to status epilepticus, a condition associated with known morbidity and mortality.

At the present time, the only approved treatment for ARS by non-healthcare professionals (caregivers) is diazepam rectal gel (Diastat®), but this preparation is associated with difficulties in administration and retention during the patient's seizure activity, inconsistent absorption, and may be objectionable for the patient and caregiver. Thus, Vanquix would provide an alternative route for immediate diazepam administration to these patients.

The efficacy and side effects of Vanquix Auto-Injector are similar to intramuscular (IM) diazepam and thus are well characterized. The pharmacokinetics of the product have been compared with those of both IM diazepam administered by conventional syringe and to Diastat®. In both instances, Vanquix Auto-Injector has been shown to have similar bioavailability. Kinetics are linear with the 5, 10, and 15 mg doses of Vanquix. A Phase 3 trial in ARS is ongoing to demonstrate efficacy and safety for FDA approval.

Clinical advantages of the Vanquix Auto-Injector for patients with ARS may include the following: 1) more consistent blood levels as the injection is administered in the lateral thigh (vastus lateralis muscle), where there is a thinner layer of subcutaneous fat; 2) the device platform offers superior stability during injection vs a conventional syringe; and 3) the entire dose has a better chance of being delivered. Improved management of ARS may be associated with fewer emergency department visits, more freedom for patients and caregivers, less cost to healthcare systems, reduced secondary events (eg, trauma), and reduced incidence of status epilepticus among these patients.