LymePak™ (doxycycline hyclate) – New drug approval

- On June 15, 2018, the FDA approved Chartwell Pharmaceuticals' LymePak (doxycycline hyclate) tablets, for the treatment of early Lyme disease (as evidenced by erythema migrans) due to *Borrelia burgdorferi* in adults and pediatric patients 8 years of age and older weighing 45 kg and above.

- Doxycycline is also available generically in the hyclate salt as capsules, tablets, delayed-release tablets, and injection; and in the monohydrate salt as capsules, tablets, and oral suspension.

    — These products are not FDA-approved for the treatment of Lyme disease. Refer to their respective drug labels for indication information.

- Doxycycline has been used in clinical practice for early stages of Lyme disease for several decades. Thorough search of the published literature identified studies in which doxycycline treatment was used for the treatment of Lyme disease.

- Over 200 patients from Lyme-disease hyperendemic areas were enrolled in five studies, and more than 100 received doxycycline. Evidence of efficacy was derived by comparing the doxycycline treatment in studies using doxycycline 100 mg twice daily for 20 - 21 days with no treatment. Clinical resolution of symptoms was defined as absence of objective late manifestations of Lyme disease, specifically those related to the musculoskeletal, nervous, and cardiac systems at 6 months.

    — In comparison to untreated patients, doxycycline-treated patients had a higher response rate at 6 months. Doxycycline-treated patients had a response rate of 75 - 95% compared to 56 - 66% in untreated patients.

- Warnings and precautions of LymePak include tooth discoloration and enamel hypoplasia; inhibition of bone growth; *Clostridium difficile* associated diarrhea; photosensitivity; severe skin reactions; Jarisch-Herxheimer reaction; intracranial hypertension; antianabolic action; development of drug resistant bacteria; and potential for microbial overgrowth.

- The most common adverse reactions with LymePak use were anorexia, nausea, vomiting, diarrhea, rash, photosensitivity, urticaria, and hemolytic anemia.

- The recommended dosage of LymePak is 100 mg orally every 12 hours for 21 days.

    — The usual dosage and frequency of administration of LymePak differs from that of the other tetracyclines. Exceeding the recommended dosage may result in an increased incidence of adverse reactions.

- Chartwell Pharmaceuticals launch plans for LymePak are pending. LymePak will be available as a 100 mg tablet.