

## Avaclyr<sup>™</sup> (acyclovir) – New orphan formulation approval

- On April 1, 2019, <u>Fera Pharmaceuticals announced</u> the FDA approval of <u>Avaclyr (acyclovir)</u> 3% ophthalmic ointment, for the treatment of acute herpetic keratitis (dendritic ulcers) in patients with herpes simplex (HSV-1 and HSV-2) virus.
- Acyclovir is also available generically as an <u>injectable solution</u>, oral <u>capsule</u>, oral <u>tablet</u>, oral <u>suspension</u>, and topical <u>ointment</u>. It is also available as a brand buccal tablet (<u>Sitavig</u>), topical cream (<u>Zovirax</u>), and in combination with hydrocortisone (<u>Xerese</u>),
  - The injection is indicated for the treatment of herpes simplex and varicella-zoster infections in immunocompromised patients; initial episodes of herpes genitalis; herpes simplex encephalitis; and neonatal herpes simplex virus infection.
  - The oral capsule, tablet and suspension are indicated for herpes zoster infections, initial and recurrent genital herpes infections, and chickenpox (varicella).
  - The ointment is indicated for the management of initial genital herpes and in limited non-lifethreatening mucocutaneous herpes simplex virus infections in immunocompromised patients.
  - Sitavig and Zovirax cream are indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent patients.
  - Xerese is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time.
- The approval of Avaclyr was based on studies that enrolled 238 subjects with dendritic herpetic keratitis.
  - Avaclyr was either superior or as effective as idoxuridine ophthalmic ointment (not approved in the U.S.) in patients with dendritic ulcers.
  - Clinical resolution (healed ulcers) at day 7 averaged 83% for Avaclyr vs. 50% for idoxuridine.
- The most common adverse reactions (2 10%) with Avaclyr use were eye pain (stinging), punctate keratitis and follicular conjunctivitis.
- The recommended dosing regimen of Avaclyr is to apply a 1 cm ribbon of ointment in the lower culde-sac of the affected eye 5 times per day (approximately every 3 hours while awake) until the corneal ulcer heals and then a 1 cm ribbon 3 times per day for 7 days.
- Fera Pharmaceuticals' launch plans for Avaclyr are pending.



## optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum<sup>®</sup> trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.