



Fera Pharmaceuticals Announces FDA Approval of Avaclyr™ (acyclovir ophthalmic ointment)

NEW YORK—April 1, 2019—The US Food and Drug Administration (FDA) has approved Fera’s New Drug Application (NDA) for Avaclyr™ (acyclovir ophthalmic ointment) 3% for the treatment of herpetic keratitis. Orphan drug exclusivity was also granted, providing seven years of marketing exclusivity for the product.

“Avaclyr approval is a major milestone for the company.” noted Frank DellaFera, Fera’s founder and President. “Working closely with the eye care community we were able to identify a need for additional options to treat herpetic keratitis. Acyclovir is the gold standard treatment in herpes virus infections so it made sense to provide this therapy in an ophthalmic dosage form¹. Fera is thankful to FDA for approving Avaclyr, making it available to physicians and patients in the US.”

Fera launch plans include finalizing its selection of a commercialization partner to provide physicians and patients access to this important therapy.

About Acute Herpetic Keratitis

According to the Center for Disease Control and Prevention (CDC), HSV (Herpes Simplex Virus) keratitis is an infection of the cornea—the clear dome that covers the colored part of the eye—that is caused by HSV. The infection usually heals without damaging the eye, but more severe infections can lead to scarring of the cornea or blindness. HSV keratitis is a major cause of blindness worldwide²⁻³.

About Avaclyr

Avaclyr (acyclovir ophthalmic ointment) 3%, is a herpes simplex virus nucleoside analog DNA polymerase inhibitor, is indicated in the treatment of acute herpetic keratitis (dendritic ulcers) in patients with herpes simplex (HSV-1 and HSV-2) virus. The most common adverse reactions (2-10%) reported in patients were eye pain (stinging), punctate keratitis and follicular conjunctivitis⁴. Please see full prescribing information.

About Fera Pharmaceuticals

Fera Pharmaceuticals is a privately held company. The company goal is to realize opportunities via acquisitions, in-licensing, developing and marketing abbreviated new drug applications (ANDAs), new drug applications (NDAs) and 505(b)(2) NDA products. For more information visit www.ferapharma.com.

References

1. Klysik K, Pietraszek A, Karewicz A and Nowakowska M, “Acyclovir in the Treatment of Herpes Viruses – A Review”, *Current Medicinal Chemistry* (2018) 25: 1. <https://doi.org/10.2174/0929867325666180309105519>.
2. Liesegang TJ. Herpes simplex virus epidemiology and ocular importance. *Cornea*. 2001;20(1):1-13.
3. Center for Disease Control (CDC). <https://www.cdc.gov/contactlenses/viral-keratitis.html#one>. Accessed April 1, 2019.
4. Avaclyr Package Insert December 2018

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