A Phase 3, Multi-center, Randomized, Double-Masked Study to Evaluate the Clinical Efficacy and Safety of SHP640 (PVP-Iodine 0.6% and Dexamethasone 0.1%) Ophthalmic Suspension Compared to PVP-Iodine and Placebo in the Treatment of Adenoviral Conjunctivitis.

Inclusion / Exclusion Criteria

INCLUSION CRITERIA	**YES**	**NO**
1. An understanding, ability, willingness to fully comply with study procedures and restrictions (by the parent(s), guardian, or legally authorized representative, if applicable).		
2. Ability to voluntarily provide written, signed, and dated (personally or via a parent(s), guardian, or legally-authorized representative(s) informed consent (and assent, if applicable) to participate in the study.		
3. Subjects of any age at Visit 1 (Note: subjects <3 months of age at Visit 1 must have been full-term, ie≥37 weeks gestational age at birth).		
4. Have a positive AdenoPlus® test at Visit 1 in at least 1 eye.		
5 Have a clinical diagnosis of suspected adenoviral conjunctivitis in at least 1 eye (the same eye as the AdenoPlus positive eye) confirmed by the presence of the following minimal clinical signs and symptoms in that same eye: • Report presence of signs and/or symptoms of adenoviral conjunctivitis for ≤ 3 days prior to Visit 1 • Bulbar conjunctival injection: a grade of ≥1 (mild) on a 0-4 Bulbar Conjunctival Injection Scale. • Watery conjunctival discharge: a grade of ≥1 (mild) on a 0-3 Watery Conjunctival Discharge Scale		
6 Be willing to discontinue contact lens wear for the duration of the study.		
7 Have a Best Corrected Visual Acuity (BCVA) of 0.60 logMAR or better in each eye as measured using an Early Treatment Diabetic Retinopathy Study (ETDRS) chart. BCVA will be assessed by an age appropriate method in accordance with the AAP Policy Statement for Visual System Assessment in Infants, Children, and Young Adults by Pediatricians (Donahue and Baker 2016; American Academy of Pediatrics 2016). The policy statement recommends formal vision screening can begin at 3 years of age. VA measurements for children under the age of 3 will be done at the discretion of the investigator. If not done, child should be able to fixate on and follow a moving object, except subjects <2 months of age who have not yet developed this ability. Subjects <2 months will be enrolled at the discretion of Investigator.		
8 Male, or non-pregnant, non-lactating female who agrees to comply with any applicable contraceptive requirements of the protocol or females of non-childbearing potential.		
EXCLUSION CRITERIA	**YES**	**NO**
1. Current or recurrent disease that could affect the action, absorption, or disposition of the investigational product, or clinical or laboratory assessments, per investigator's discretion.		
2. Current or relevant history of physical or psychiatric illness, any medical disorder that may make the subject unlikely to fully complete the study, or any condition that presents undue risk from the investigational product or procedures.		
3. Have known or suspected intolerance or hypersensitivity to the investigational product, closely related compounds, or any of the stated ingredients.		
4. Prior enrollment in a FST-100 or SHP640 clinical study.		
5. Subjects who are employees, or immediate family members of employees (who are directly related to study conduct), at the investigational site.		
6. Have a history of ocular surgical intervention within ≤6 months prior to Visit 1 or planned for the period of the study.		

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7. Have a preplanned overnight hospitalization during the period of the study.		
8. Have presence of any intraocular, corneal, or conjunctival ocular inflammation (eg, uveitis, iritis, ulcerative keratitis, chronic blepharoconjunctivitis), other than adenoviral conjunctivitis.		
9. Have presence of corneal subepithelial infiltrates at Visit 1.		
10. Have active or history of ocular herpes.		
11. Have at enrollment or within ≤30 days of Visit 1, a clinical presentation more consistent with the diagnosis of ocular allergy, toxic conjunctivitis, or non-adenoviral ocular infection (eg, bacterial, fungal, acanthamoebal, other or parasitic).		
12. Neonates or infants (i.e. subjects less than 12 months of age) who have suspected or confirmed (based on the result of any test conducted prior to screening) conjunctivitis of gonococcal, chlamydial, herpetic or chemical origin.		
13. Neonates or infants (i.e. subjects less than 12 months of age) whose birth mothers had any sexually transmitted disease within 1 month of delivery or any history of genital herpes.		
14. Presence of nasolacrimal duct obstruction at Visit 1 (Day 1).		
15. Presence of any significant ophthalmic condition (e.g., Retinopathy of Prematurity, congenital cataract, congenital glaucoma) or other congenital disorder with ophthalmic involvement that could affect study variables.		
16. Be a known intraocular pressure (IOP) steroid responder, have a known history of glaucoma, be a glaucoma suspect, or have a known history of an elevated IOP > 21 mmHg.		
17. Have any known clinically significant optic nerve defects.		
18. Have a history of recurrent corneal erosion syndrome, either idiopathic or secondary to previous corneal trauma or dry eye syndrome; presence of corneal epithelial defect or any significant corneal opacity at Visit 1.		
19. Presence of significant, active condition in the posterior segment which requires invasive treatment (e.g., intravitreal treatment with VEGF inhibitors or corticosteroids) and may progress during the study participation period.		
20. Have used any topical ocular or systemic anti-virals or antibiotics within ≤7 days of enrollment.		
21. Have used any topical ocular NSAIDs within ≤1 day of enrollment.		
22. Have used any topical ophthalmic steroids in the last ≤14 days.		
23. Have used any systemic corticosteroid agents within ≤14 days of Day 1. Stable (initiated ≥30 days prior to enrollment) use of inhaled and nasal corticosteroids is allowed, given no anticipated change in dose for the duration of the study. Topical dermal steroids are allowed except in the peri-ocular area.		
24. Have used non-corticosteroid immunosuppressive agents within ≤14 days of Day 1.		

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25. Have used any topical ophthalmic products, including tear substitutes, and over-the-counter preparations such as lid scrubs, within 2 hours of Visit 1 and be unable to discontinue all topical ophthalmic products for the duration of the study. Use of hot or cold compresses is also not permitted during the study.		
26. Have any significant ocular disease (e.g., Sjogren's syndrome) or any uncontrolled systemic disease or debilitating disease (e.g., cardiovascular disease, hypertension, sexually transmitted diseases/infections, diabetes or cystic fibrosis), that may affect the study parameters, per Investigator's discretion.		
27. Any known history of immunodeficiency disorder or known active conditions predisposing to immunodeficiency, such as human immunodeficiency virus, hepatitis B or C, evidence of active hepatitis A (antihepatitis A virus immunoglobulin M), or organ or bone marrow transplantation.		
28. Within 30 days prior to the first dose of investigational product: • Have used an investigational product or device, or • Have been enrolled in a clinical study (including vaccine studies) that, in the investigator's opinion, may impact this Shire-sponsored study.		

COMMENTS: _____
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