November 2, 2020

Aurinia Announces Outcome of AUDREY™ Clinical Trial in Dry Eye Syndrome

- The trial did not achieve statistical significance on the primary endpoint of ≥ 10mm improvement in Schirmer Tear Test *(STT) at 4 weeks –*
- Company to suspend development program for voclosporin ophthalmic solution (VOS) -
- Aurinia to host conference call today at 4:30 p.m. EST -

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (Nasdaq: AUPH / TSX:AUP) (“Aurinia” or the “Company”), a late-stage clinical biopharmaceutical company, today announced topline data from the Phase 2/3 AUDREY™ clinical study evaluating voclosporin ophthalmic solution (VOS) for the potential treatment of dry eye syndrome (DES). The trial did not achieve statistical significance on its primary endpoint of a 10mm or greater improvement in STT at four weeks between active dose groups of VOS compared to vehicle. Aurinia is suspending the development program for VOS based upon these results.

“First and foremost, we would like to thank the patients and investigators who participated in the AUDREY clinical trial. Based upon these initial topline results that we continue to interrogate, we are suspending the DES program at this time,” commented Peter Greenleaf, President and Chief Executive Officer of Aurinia. “While surprised by these results, we remain focused on preparing voclosporin for lupus nephritis – which has a different formulation and delivery mechanism compared to VOS. As we approach our lupus nephritis PDUFA action date, the Aurinia team remains committed to our mission of developing novel treatments for people with debilitating and severe autoimmune disease.”

The AUDREY trial was a randomized, double-masked, vehicle-controlled, dose-ranging study evaluating the efficacy and safety of VOS in subjects with DES. A total of 508 subjects were enrolled. The study consisted of four arms with a 1:1:1:1 randomization schedule, in which patients received either 0.2% VOS, 0.1% VOS, 0.05% VOS or vehicle, dosed twice daily for 12 weeks. The primary outcome measure for the trial was the proportion of subjects with a 10mm or greater improvement in STT at four weeks.

	Measure	**Result (%)**	**Odds-Ratio (vs. vehicle) [95% CI]**	**p-value (vs. vehicle)**
Primary Endpoint	Percentage of patients with a ≥ 10mm improvement from baseline in a Schirmer Tear Test at 4 weeks	VOS 0.05% =10%	2.18 [0.62, 7.62]	p = 0.09
		VOS 0.1% = 9%	1.78 [0.49, 6.45]	p = 0.28
		VOS 0.2% = 11%	2.48 [0.70, 8.30]	p = 0.13
		Vehicle = 5%	N/A	N/A

“While we are understandably disappointed that VOS did not achieve the primary endpoint of the AUDREY trial, we uncovered important learnings about this disease state, particularly concerning the patient population with severe dry eye syndrome,” commented Neil Solomons, M.D., Chief Medical Officer.

Secondary outcome measures evaluated in the trial included STT at other time points, Fluorescein Corneal Staining (FCS) at multiple time points, change in eye dryness, burning/stinging, itching, photophobia, eye pain and foreign body sensation at multiple time points, and additional safety endpoints. Initial analysis of these secondary outcomes suggests dose-dependent activity and safety were observed across dose groups compared to vehicle. Further analysis of the AUDREY dataset will be conducted over the coming weeks.

Conference Call Information

Aurinia will host a conference call and webcast to discuss these results today, Monday, November 2, 2020 at 4:30 p.m. EST. The webcast can be accessed on the investor section of the Aurinia website at www.auriniapharma.com. To participate in the teleconference, please dial +1-877-407-9170 (Toll-free U.S. & Canada).

About Aurinia

Aurinia Pharmaceuticals is a late-stage clinical biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company is currently seeking FDA approval of voclosporin for the potential treatment of LN. The Company’s head office is in Victoria, British Columbia and its U.S. commercial hub is in Rockville, Maryland. The Company focuses its development efforts globally.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20201102005888/en/

Investors & Corporate:
Glenn Schulman, PharmD, MPH
Corporate Communications, Aurinia
gschulman@auriniapharma.com

Media:
Stefan Riley
Ten Bridge Communications
stefan@tenbridgecommunications.com

Source: Aurinia Pharmaceuticals Inc.