Aurinia Announces Voclosporin Ophthalmic Solution Demonstrates Statistically Superior Efficacy Versus Restasis® in a Phase 2 Head-to-Head Study for the Treatment of Dry Eye Syndrome

- **VOS showed statistical superiority to Restasis® on FDA-accepted objective signs of DES**
- **42.9% of VOS subjects vs 18.4% of Restasis® subjects (p=.0055) demonstrated ≥ 10mm improvement in STT at Week 4**
- **Primary endpoint of drop discomfort at 1-minute on Day 1 showed no statistical difference between VOS and Restasis®, as both exhibited low drop discomfort scores**
- **Aurinia to advance VOS for the treatment of DES**

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH/TSX:AUP), a clinical stage biopharmaceutical company focused on the global immunology market, today announced positive results for its exploratory Phase 2 head-to-head study evaluating the efficacy, safety and tolerability of voclosporin ophthalmic solution (VOS 0.2%) versus Restasis®(cyclosporine ophthalmic emulsion 0.05%) for the treatment of dry eye syndrome (DES). Both drugs were shown to be well-tolerated and there was no statistical difference between VOS and Restasis® for the primary endpoint as both drugs exhibited low drop discomfort scores.

On the key pre-specified secondary endpoints of Schirmer Tear Test/STT (an objective measure of tear production), and Fluorescein Corneal Staining/FCS (an objective measure of structural damage to the cornea), which are FDA-accepted efficacy endpoints, VOS showed rapid and statistically significant improvements over Restasis® at Week 4 (STT: p=.0051; FCS: p=.0003).

This 100-patient, double-masked, head-to-head study was designed to evaluate the efficacy, safety and tolerability of VOS versus Restasis® in subjects with DES. Both arms of the study received either VOS or Restasis® (1:1) administered twice daily, in both eyes, for 28 days. Key pre-specified secondary endpoints, which are FDA-accepted endpoints, include STT, FCS, and assessments of dry eye symptoms.
**4-Week Pre-Specified Efficacy Endpoints (Signs)**

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<th>VOS</th>
<th>Restasis®</th>
<th>(p)-value vs. Restasis®</th>
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<tbody>
<tr>
<td><strong>Schirmer Tear Test (STT)</strong></td>
<td>8.6</td>
<td>3.3</td>
<td>.0051</td>
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<tr>
<td>(mm LS mean increase from baseline)</td>
<td></td>
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<tr>
<td>% of subjects showing ≥ 10mm improvement in STT</td>
<td>42.9%</td>
<td>18.4%</td>
<td>.0055</td>
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(basis of FDA approval for other CNIs and an improvement is considered to be clinically significant)

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<tr>
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<th>VOS</th>
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<th>(p)-value</th>
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<tr>
<td><strong>Fluorescein Corneal Staining (FCS)</strong></td>
<td>-2.2</td>
<td>-0.2</td>
<td>.0003</td>
</tr>
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(reduction in staining is clinically significant)

*worst eye

Both treatment arms also demonstrated substantial and statistically significant improvements on the Symptom Assessment in Dry Eye (SANDE) score from baseline to Week 4.

No serious adverse events were reported in the study, and there were no unexpected safety signals.

“Improvements in STT and FCS are considered by regulators to be two of the most clinically meaningful measures of efficacy in this disease. The rapid onset and overall efficacy (as measured by the STT and FCS) demonstrated by VOS in this head-to-head study conducted against Restasis® is astounding and could be a game changer in the treatment landscape for dry eye,” said Joseph Tauber, M.D., Principal Investigator and head of the renowned Tauber Eye Institute in Kansas City, MO.

Neil Solomons, M.D., Aurinia’s Chief Medical Officer said, “We are extraordinarily excited with the superior efficacy shown by VOS when compared to Restasis®, which is the current market leader for the treatment of DES in the US. The efficacy endpoints exceeded our expectations and provide further validation of the potential of VOS to provide a highly differentiated and efficacious treatment option for the more than 16 million patients living with this all-too-common disease.”

“Based on these positive data, we plan to aggressively advance VOS for the treatment of DES, which we believe can create considerable value for both patients and our shareholders,” said Richard M. Glickman, Chairman and CEO of Aurinia. “Our pursuit of further development of VOS provides the company with an enhanced pipeline that further capitalizes on the differentiating features of voclosporin and positions us for substantial growth.”

Aurinia will present the results of the clinical trial during a conference call and webcast presentation to be held at 8:00am ET Tuesday, January 22, 2019. A link to the live webcast and slides will be available on the Investors section of the Company’s website at [http://www.auriniapharma.com](http://www.auriniapharma.com).

**About Aurinia**

Aurinia Pharmaceuticals Inc. is a clinical stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are
suffering from serious diseases with a high unmet medical need. The company is currently developing voclosporin, an investigational drug, for the potential treatment of lupus nephritis (LN), focal segmental glomerulosclerosis (FSGS), and dry eye syndrome (DES). The company is headquartered in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at www.auriniapharma.com.

About VOS
VOS (voclosporin ophthalmic solution) is an aqueous, preservative free nanomicellar solution containing 0.2% voclosporin intended for use in the treatment of DES. Studies have been completed in rabbit and dog models, and a single Phase I has also been completed in healthy volunteers and patients with DES. VOS has IP protection until 2031.

About Dry Eye Syndrome (DES)
Dry eye syndrome (DES) is a chronic disease and is characterized by irritation and inflammation that occurs when the eye’s tear film is compromised by reduced tear production, imbalanced tear composition, or excessive tear evaporation. The impact of DES ranges from subtle, yet constant eye irritation to significant inflammation and scarring of the eye’s surface. Discomfort and pain resulting from DES can reduce quality of life and cause difficulty reading, driving, using computers and performing daily activities. While there are FDA approved therapies available for the treatment of DES, there is opportunity for potential improvement in the efficacy in addition to other measures such as onset of action, tolerability and dosing.

About Voclosporin
Voclosporin, an investigational drug, is a novel and potentially best-in-class CNI with clinical data in over 2,400 patients across indications. Voclosporin is an immunosuppressant, with a synergistic and dual mechanism of action. By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses and stabilizes the podocyte in the kidney. It has been shown to have a more predictable pharmacokinetic and pharmacodynamic relationship (potentially requires no therapeutic drug monitoring), an increase in potency (vs cyclosporin), and an improved metabolic profile compared to legacy CNIs. Aurinia anticipates that upon regulatory approval, patent protection for voclosporin will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027 under the Hatch-Waxman Act and comparable laws in other countries and until April 2028 with anticipated pediatric extension.

About Restasis®
RESTASIS® and RESTASIS MULTIDOSE™ Ophthalmic Emulsion help increase your eyes' natural ability to produce tears, which may be reduced by inflammation due to Chronic Dry Eye. RESTASIS® and RESTASIS MULTIDOSE™ did not increase tear production in patients using anti-inflammatory eye drops or tear duct plugs. https://www.restasis.com/.

Forward-Looking Statements
Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: Voclosporin Ophthalmic Solution (VOS) and the data as it relates to the phase 2 study: voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity, the development of VOS creating considerable value for patients and Aurinia’s
shareholders; Aurinia being positioned for substantial growth; there being opportunities for improvement of efficacy, onset of action, tolerability and closing in DES; VOS being a game changer in the treatment landscape for dry eye; efficacy findings of VOS; the patent life for Aurinia’s patents; and the potential to extend that patent life on the occurrence of certain events. It is possible that such results or conclusions may change based on further analyses of these data. Words such as “anticipate”, “will”, “believe”, “estimate”, “expect”, “intend”, “target”, “plan”, “goals”, “objectives”, “may” and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: that another company will not create a substantial competitive product for Aurinia’s LN or DES business without violating Aurinia’s intellectual property rights; the burn rate of Aurinia’s cash for operations; the costs and expenses associated with Aurinia’s clinical trials; the planned studies achieving positive results; Aurinia being able to extend its patents on terms acceptable to Aurinia; and the size of the LN or DES market. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: difficulties, delays, or failures we may experience in the conduct of our AURORA, FSGS or DES clinical trials; difficulties we may experience in completing the development and commercialization of voclosporin or VOS; the market for the LN or DES business may not be as estimated; Aurinia may have to pay unanticipated expenses; estimated costs for clinical trials may be underestimated, resulting in Aurinia having to make additional expenditures to achieve its current goals; Aurinia not being able to extend or protect its patent portfolio for voclosporin or VOS; and competitors may arise with similar or more competitive products. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

Except as required by law, Aurinia will not update forward-looking information. All forward-looking information contained in this press release is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business can be found in Aurinia’s most recent Annual Information Form available by accessing the Canadian Securities Administrators’ System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com or the U.S. Securities and Exchange Commission’s Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar.
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