

RVL Pharmaceuticals Announces Santen Obtains Manufacturing and Marketing Approval in Japan for UPNEEQ® Mini Ophthalmic Solution 0.1%

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RVL Pharmaceuticals, Inc →

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BRIDGEWATER, N.J., Jan. 8, 2026 /PRNewswire/ -- RVL Pharmaceuticals, Inc. and its affiliates (together, "RVL") announces Santen Pharmaceutical Co., Ltd. ("Santen"), a leading ophthalmology company has obtained the manufacturing and marketing approval in Japan for *UPNEEQ® Mini Ophthalmic Solution 0.1%* (generic name: oxymetazoline hydrochloride; development code: STN1013800; hereinafter the product), a treatment for acquired blepharoptosis (low-lying eyelids).

This milestone expands access in Japan to the first approved non-invasive treatment for blepharoptosis, where treatment options have primarily been limited to surgical procedures. In the U.S. market, Upneeq® is the first and only FDA-approved prescription eye drop for acquired blepharoptosis (low-lying eyelids), and continues to demonstrate strong patient satisfaction, increased adoption, and channel diversification.

"UPNEEQ® was developed to provide patients with a meaningful, non-invasive alternative to eyelid surgery," said Lori Deo, Chief Executive Officer of RVL Pharmaceuticals. "Our partnership with Santen allows us to extend this innovation to patients in Japan. Together, we are addressing a significant unmet need and helping advance new standards of care for acquired blepharoptosis."

Approval in Japan was supported by a Phase 3, placebo-controlled, randomized, double-masked study conducted in Japan, the efficacy and safety of once-daily administration of the product were evaluated in patients with acquired blepharoptosis. The superiority of the product was demonstrated in the primary

endpoint - a change from baseline at 2 hours after administration in MRD-1 (Marginal Reflex Distance-1, the margin between the upper eyelid and the center of the pupil)* at Day 14 after the start of treatment—in the once-daily group versus the placebo eye drop group. In addition, an exploratory analysis showed that improvement in MRD-1 persisted for more than 8 hours after instillation. No serious adverse effects or adverse effects leading to treatment discontinuation were observed during the study. In the Phase 3 clinical trial in Japan (once-daily instillation for 6 months), no trend toward weakening of the eyelid-lifting effect or rebound effect was observed.

* In this clinical study, MRD-1 was defined as the distance from the center of the pupil to the upper eyelid margin, as determined from anterior segment photographs.

About Upneeq® in the United States

Upneeq® (oxymetazoline hydrochloride ophthalmic solution), 0.1% is a prescription eyedrop used to treat acquired blepharoptosis (low-lying lids) in adults. The product was approved in the US by the FDA in July 2020.

Important Safety Information

Low-lying lids may be related to conditions such as stroke and/or brain aneurysm, Horner syndrome, myasthenia gravis, loss of the ability to move eye muscles, eye infection and eye tumors. Tell your doctor if you have any of these conditions.

UPNEEQ is a type of medication that may affect your blood pressure. If you have heart disease, uncontrolled high or low blood pressure, or feel faint at rest or when quickly standing up, you should call your doctor if your symptoms get worse.

Patients with reduced blood flow to the brain or heart, or patients who experience eye or mouth dryness due to an immune system disorder (Sjögren's syndrome), should use care when taking UPNEEQ. Call your doctor immediately if you feel your symptoms may be getting worse.

UPNEEQ may increase the risk of eye pressure due to fluid buildup (angle-closure glaucoma) in patients with untreated narrow-angle glaucoma. Call your doctor immediately if you feel increased pressure in your eye after using UPNEEQ.

Do not let the tip of the UPNEEQ vial touch your eye or any other surface. This can help prevent eye injury or contamination. Each UPNEEQ vial is for one-time use and should be discarded after being used.

The most common adverse reactions with UPNEEQ (occurring in 1–5% of patients) were eye inflammation, eye redness, dry eye, blurred vision, eye pain at time of use, eye irritation, and headache.

This is a summary of the most important safety information for UPNEEQ. For more in-depth safety information, please review the full U.S. **Prescribing Information** for UPNEEQ.

About RVL Pharmaceuticals

RVL Pharmaceuticals, Inc operates a digitally enabled, vertically integrated commercial platform spanning product acquisition through order fulfillment, meeting consumers and healthcare providers where they are.

Its lead product, Upneeq®, provides a non-surgical eyelift for adults with acquired ptosis. Upneeq® activates a muscle in the eyelids, lifting the lid for a more open and awake look. One drop daily is clinically proven to provide visible results in as fast as 5 minutes and lasts up to 8 hours.

In July 2020, Osmotica Pharmaceuticals plc (due to a company name change, currently known as RVL Pharmaceuticals, Inc.), entered into an exclusive license agreement with Santen, covering the continued development, registration, and commercialization rights for RVL-1201, a 0.1% oxymetazoline hydrochloride ophthalmic solution, in Japan and certain other international markets. Santen has been developing the product as STN1013800.

For more information, please visit **www.rvlpharma.com**.

About Santen



Santen is a global pharmaceutical company committed to advancing eye health and improving lives through better vision. Founded in 1890 in Osaka, Japan, Santen makes use of more than 135 years of experience in research and development, manufacturing, and marketing of pharmaceuticals and medical devices to help people around the globe maintain and improve their eye health. Santen focuses exclusively on eye health and its portfolio includes glaucoma, dry eye, infection, allergy, age-related macular degeneration, and myopia. Santen's products and services are available in more than 60 countries and regions. Guided by its Core Principle "*Tenki ni sanyo suru*" – Exploring the secrets and mechanisms of nature in order to contribute to people's health – Santen combines its expertise with deep patient focus to contribute to the realization of "Happiness with Vision."

For more information, please visit <https://www.santen.com/en>

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