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## **QBREXZA® (Rapifort® Wipes 2.5%) Receives Manufacturing and Marketing Approval in Japan Triggering \$2.5 Million Milestone Payment to Journey Medical Corporation**

SCOTTSDALE, Ariz., Feb. 11, 2022 (GLOBE NEWSWIRE) -- Journey Medical Corporation (NASDAQ: DERM) ("Journey Medical"), a commercial-stage pharmaceutical company that focuses on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions, today announced that it received notice from its exclusive licensing partner in Japan, Maruho Co., Ltd. ("Maruho"), that Japan's Ministry of Health, Labor and Welfare ("MHLW") approved Rapifort® Wipes 2.5% (glycopyrronium tosylate hydrate) for the treatment of primary axillary hyperhidrosis. This approval triggers a milestone payment of \$10 million to Journey Medical, \$7.5 million of which will be paid to Dermira, Inc. ("Dermira"), a wholly-owned subsidiary of Eli Lilly and Company, pursuant to the terms of the Asset Purchase Agreement between Journey and Dermira, with net proceeds of \$2.5 million to Journey. Pursuant to the terms of the agreement with Maruho, the milestone payment is due from Maruho within 30 days. Journey Medical acquired global rights to QBREXZA® from Dermira in 2021.

Claude Maraoui, President and Chief Executive Officer of Journey Medical, stated, "The manufacturing and marketing approval of Rapifort Wipes 2.5% in Japan activates a milestone payment to Journey Medical which adds a revenue stream beyond U.S. product sales for the company. We are very pleased that Rapifort Wipes 2.5% will be commercialized in Japan, providing more people access to this beneficial prescription cloth towelette for the treatment of primary axillary hyperhidrosis."

QBREXZA is a topical product approved by the U.S. Food and Drug Administration for treatment of primary axillary hyperhidrosis in adult and pediatric populations (ages nine-years and older) and is self-administered by patients. Additionally, QBREXZA is noted as a first-line therapy for primary axillary hyperhidrosis by the International Hyperhidrosis Society.

Hyperhidrosis is a condition of sweating beyond what is physiologically required for normal thermal regulation and affects an estimated 4.8% of the U.S. population, or approximately 15 million people.<sup>1</sup> Of these, 65 percent, or nearly 10 million people, suffer from sweating localized to the underarms (axillary disease). Studies have demonstrated that excessive sweating often impedes normal daily activities and can also result in occupational, emotional, psychological, social and physical impairment.<sup>1,2</sup>

For additional information about QBREXZA, please visit <https://www.QBREXZA.com/>.

### **About QBREXZA® (glycopyrronium) cloth**

QBREXZA (pronounced kew brex' zah) is an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adult and pediatric patients, nine years of age and older. QBREXZA is applied directly to the skin and is designed to block sweat production by inhibiting sweat gland activation. For more information visit [www.QBREXZA.com](https://www.QBREXZA.com).

### **Important Safety Information**

**Contraindications:** QBREXZA is contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of QBREXZA (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome).

### **Warnings and Precautions**

**Worsening of Urinary Retention:** QBREXZA should be used with caution in patients with a history or presence of documented urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, distended bladder), especially in patients with prostatic hypertrophy or bladder-neck obstruction. Instruct patients to discontinue use immediately and consult a physician should any of these signs or symptoms develop. Patients with a history of urinary retention were not included in the clinical studies.

**Control of Body Temperature:** In the presence of high ambient temperature, heat illness (hyperpyrexia and heat stroke due to decreased sweating) can occur with the use of anticholinergic drugs such as QBREXZA. Advise patients using QBREXZA to watch for generalized lack of sweating when in hot or very warm environmental temperatures and to avoid use if not sweating under these conditions.

**Operating Machinery or an Automobile:** Transient blurred vision may occur with use of QBREXZA. If blurred vision occurs, the patient should discontinue use until symptoms resolve. Patients should be warned not to engage in activities that require clear vision such as operating a motor vehicle or other machinery or performing hazardous work until the symptoms have resolved.

### **Adverse Reactions**

The most common adverse reactions seen in  $\geq 2\%$  of subjects treated with QBREXZA were dry mouth (24.2%), mydriasis (6.8%), oropharyngeal pain (5.7%), headache (5.0%), urinary hesitation (3.5%), vision blurred (3.5%), nasal dryness (2.6%), dry throat (2.6%), dry eye (2.4%), dry skin (2.2%) and constipation (2.0%). Local skin reactions, including erythema (17.0%), burning/stinging (14.1%) and pruritus (8.1%) were also common.

### **Drug Interactions**

**Anticholinergics:** Coadministration of QBREXZA with anticholinergic medications may result in additive interaction leading to an increase in anticholinergic adverse effects. Avoid coadministration of QBREXZA with other anticholinergic-containing drugs.

### **Instructions for Administering QBREXZA**

Instruct patients to use one cloth to apply QBREXZA to both axillae by wiping the cloth across one underarm, ONE TIME. Using the same cloth, apply the medication to the other

underarm, ONE TIME. Inform patients that QBREXZA can cause temporary dilation of the pupils and blurred vision if it comes in contact with the eyes.

Instruct patients to wash their hands with soap and water immediately after discarding the used cloth.

### **Use in Specific Populations**

**Pregnancy:** There are no available data on QBREXZA use in pregnant women to inform a drug-associated risk for adverse developmental outcomes.

**Lactation:** There are no data on the presence of glycopyrrolate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for QBREXZA and any potential adverse effects on the breastfed infant from QBREXZA or from the underlying maternal condition.

**Renal Impairment:** The elimination of glycopyrronium is severely impaired in patients with renal failure.

Please see [Full Prescribing Information](#)

### **About Journey Medical Corporation**

Journey Medical Corporation (NASDAQ: DERM) ("Journey Medical") is focused on identifying, acquiring, developing and strategically commercializing innovative, differentiated dermatology products through its efficient sales and marketing model. The company currently markets nine products that help treat and heal common skin conditions. The Journey Medical team is comprised of industry experts with extensive experience commercializing some of the most successful prescription dermatology brands. Journey Medical is located in Scottsdale, Arizona and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). Journey is registered under the Securities Exchange Act of 1934, as amended, and files periodic reports with the U.S. Securities and Exchange Commission ("SEC"). For additional information about Journey Medical, visit [www.journeymedicalcorp.com](http://www.journeymedicalcorp.com).

### **Forward-Looking Statements**

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words "we", "us" and "our" may refer to Journey Medical. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain

additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying mutatis mutandis to every other instance of such information appearing herein.

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1. *Doolittle et. al., Hyperhidrosis: An Update on Prevalence and Severity in the United States. Arch Dermatol Res. 308:743-749, 2016.*
2. *Kamudoni, et al., The impact of hyperhidrosis on patients' daily life and quality of life: a qualitative investigation. Health and Quality of Life Outcomes, 15(1). 2017.*



Source: Journey Medical Corporation