Viatris Announces the Launch of RYZUMVI™ (Phentolamine Ophthalmic Solution) 0.75% in the United States

April 1, 2024

PITTSBURGH, April 1, 2024 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a global healthcare company, today announced the U.S. commercial launch of RYZUMVI ™ (phentolamine ophthalmic solution) 0.75% for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents in the United States. RYZUMVI is now the only U.S. commercially available FDA-approved eye drop to reverse dilation.[1]

According to the American Academy of Ophthalmology and the American Optometric Association, clinical practice guidelines recommend dilation as a standard of care.[2,3] Dilation allows eye care professionals to identify both common and serious eye health issues, including signs of systemic disease.[2,3] The average time of dilation lasts three to eight hours, but can last up to 24 hours in some people.[4,5] Prolonged dilation may lead to patients refusing dilation.[6,7]

Comprehensive dilated eye exams play a vital role in detecting potential vision-impairing ophthalmic conditions such as cataracts and potentially blinding diseases like glaucoma, diabetic retinopathy, and age-related macular degeneration.[2,3] Additionally, comprehensive dilated eye exams can uncover evidence of systemic diseases like diabetes, rheumatoid arthritis, and hypertension.[2,3]

The U.S. Food and Drug Administration (FDA) approved RYZUMVI in September 2023. RYZUMVI was evaluated across 2 randomized, vehicle-controlled, double-masked MIRA-2 and MIRA-3 clinical trials in which patients (N=553) aged 12 to 80 years who had mydriasis induced by instillation of phenylephrine, tropicamide, or PAREMYD® (hydroxyamphetamine hydrobromide and tropicamide) were administered 2 drops (in the study eye) or 1 drop (in the fellow eye) of either RYZUMVI or placebo one hour after instillation of the mydriatic agent.

The onset of action of RYZUMVI generally occurs in 30 minutes. In the MIRA-2 and MIRA-3 clinical trials, at 90 minutes after administration, 49% and 58% of patients administered 2 drops of RYZUMVI returned to ≤ 0.2 mm of baseline pupil diameter compared to 7% and 6% of patients administered placebo, respectively. In the MIRA-2 trials' placebo group, 34% of patients were still dilated (had not returned to ≤ 0.2 mm of baseline pupil diameter) at 24 hours. In the MIRA-3 trials' placebo group, 28% of patients were still dilated at 24 hours.[1]

RYZUMVI is not recommended to be used in patients with active ocular inflammation (e.g., iritis). To avoid the potential for eye injury or contamination, care should be taken to avoid touching the vial tip to the eye or to any other surface. Contact lens wearers should be advised to remove their lenses prior to the instillation of RYZUMVI and wait 10 minutes after dosing before reinserting their contact lenses.[1]

The most common adverse reactions that have been reported are instillation site discomfort (16%), conjunctival hyperemia (12%), and dysgeusia (6%).

For more information on RYZUMVI, visit https://www.ryzumvi.com/.

About Pharmacologically-Induced Mydriasis

An estimated 100 million eye dilations are conducted every year in the U.S. to examine the retina (back-of-the-eye) either for routine check-ups, disease monitoring or surgical procedures.[8] Recovery from pharmacologically-induced mydriasis can take three to eight hours, and sometimes lasts 24 hours.[4,5]

About RYZUMVI ™ (Phentolamine Ophthalmic Solution) 0.75%

Indication
RYZUMVI™ (phentolamine ophthalmic solution) 0.75% is indicated for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents.

Important Safety Information

Warnings and Precautions

- **Uveitis**: RYZUMVI is not recommended to be used in patients with active ocular inflammation (e.g., iritis).
- **Potential for Eye Injury or Contamination**: To avoid the potential for eye injury or contamination, care should be taken to avoid touching the vial tip to the eye or to any other surface.
- **Use with Contact Lenses**: Contact lens wearers should be advised to remove their lenses prior to the instillation of RYZUMVI and wait 10 minutes after dosing before reinserting their contact lenses.

Adverse Reactions
The most common adverse reactions that have been reported are instillation site discomfort (16%), conjunctival hyperemia (12%), and dysgeusia (6%).

Click here for full Prescribing Information.

Forward Looking Statements

This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward looking statements may include statements regarding the U.S. commercial launch of RYZUMVI™ inthe United States and that RYZUMVI is now the only U.S. commercially available FDA-approved eye drop to reverse dilation. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatris' ability to bring new products to market, including but not limited to "at-risk" launches; Viatris' or its partners' ability to develop, manufacture, and commercialize products; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings; the possibility that Viatris may be unable to realize the intended benefits of, or achieve the intended goals or outlooks with respect to, its strategic initiatives; the possibility that Viatris may be unable to achieve intended or expected benefits, goals, outlooks, synergies, growth opportunities and operating efficiencies in connection with divestitures, acquisitions, other transactions or restructuring programs, within the expected timeframes or at all; goodwill or impairment charges or other losses related to the divestiture or sale of businesses or assets; Viatris' failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics; any significant breach of data security or data privacy or disruptions to our information technology systems; risks associated with international operations; the ability to protect intellectual property and preserve intellectual property rights; changes in third-party relationships; the effect of any changes in Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris or its partners; uncertainties and matters beyond the control of management, including general economic conditions, inflation and exchange rates; failure to execute stock repurchases consistent with current expectations; stock price volatility; and the other risks described in Viatris' filings with the Securities and Exchange Commission (SEC). Viatris routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatris undertakes no obligation to update these statements for revisions or changes after the date of this press release other than as required by law.

About Viatris
Viatris Inc. (NASDAQ: VTRS) is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, currently supplying high-quality medicines to approximately 1 billion patients around the world annually and touching all of life's moments, from birth to the end of life, acute conditions to chronic diseases. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a-kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatris. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at **viatris.com** and **investor.viatris.com**, and connect with us on **LinkedIn**, **Instagram**, **YouTube** and **X** (formerly Twitter).

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