Viatris Statement Regarding Receipt of Warning Letter and Import Alert for Indore, India Facility

December 23, 2024

PITTSBURGH, Dec. 23, 2024 –

Our plants around the world are regularly inspected by health authorities to ensure compliance with the various markets we serve. Following an inspection by the U.S. FDA at our oral finished dose manufacturing facility in Indore, India earlier this year, the Agency has issued a Warning Letter, and an Import Alert related to this facility.

The Import Alert affects 11 actively distributed products that will no longer be accepted into the U.S. until the Warning Letter is lifted. It makes exceptions, subject to certain conditions, for four products based on shortage concerns. There could be the potential for additional exceptions based on further discussions with the Agency.

Following the substance of FDA's original inspection observations, we immediately implemented a comprehensive remediation plan at the site. The necessary corrective and preventive actions are well underway, including but not limited to related personnel actions. Additionally, we have engaged independent third-party subject matter experts to support the remediation plan.

We have been in regular communication with FDA during this process and will continue to work to ensure that the Agency is satisfied with the steps we have taken to resolve all the points raised. Our response to the Warning Letter and Import Alert will be submitted within the required time periods.

At this time, we do not anticipate these actions impacting our current 2024 financial guidance ranges. We will incorporate potential future financial impact in our 2025 guidance ranges when we provide these in early 2025.

We take very seriously our continued and comprehensive oversight of our entire manufacturing network. Patient safety remains our primary and unwavering focus. We will work closely with our customers to mitigate any possible supply disruptions and meet the needs of the patients we serve.

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 receipt of Warning Letters and Import Alerts; exceptions to the Import Alert; our remediation plan; corrective and preventative actions; responses to the warning letter and related steps; our financial guidance; potential future financial impact; and possible supply disruptions and related impacts. 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; our ability to comply with applicable laws and regulations; 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; 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; Viatris' failure to achieve expected or targeted future financial and operating performance and results; risks associated with international operations; 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; 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.

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