Bayer Issues Voluntary Recall Nationwide of Vitrakvi® (larotrectinib) Oral Solution 20 mg/mL Due to Presence of Microbial Contamination

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At Magellan Rx Management, we want to help you receive the best possible care. Visit our drug recall site for details: https://www1.magellanrx.com/drug-recalls/.

About this recall:
Bayer is voluntarily recalling **1 lot** of Vitrakvi® (larotrectinib) oral solution 20 mg/mL in 100 mL glass bottles to the consumer/user level. The recall is due to contamination that was found during testing of the product. Contamination was from the fungus *Penicillium brevicompactum*. **The recalled lot of Vitrakvi has an NDC of 50419-0392-01 and is identified as lot# 2114228 with an expiration date of February 29, 2024.**

Vitrakvi is FDA-approved for the treatment of solid tumors that are *NTRK* gene fusion positive. Therefore, it is expected that patients receiving this medication may have a suppressed immune system.

What this means to you:
Cases of severe disease caused by similar fungus species to *Penicillium brevicompactum* have occurred, especially in patients whose immune systems are suppressed. Therefore, the potential exists that ingestion of *Penicillium brevicompactum* in patients with underlying immune system suppression could result in serious fungal infections of the blood or pneumonia that can be life-threatening.

Consumers who have the recalled Vitrakvi product should immediately stop use of this particular lot and contact their healthcare provider if they have any questions, concerns, or have experienced any problems related to the recalled drug. Patients or prescribers who have questions regarding the recall can contact Bayer Medical Information Call Center at 888-842-2937, Monday to Friday between the hours of 8:30 a.m. and 8:00 p.m. Eastern Standard Time. Alternatively, patients with general questions regarding this recall can contact Qualanex via e-mail at Recall@qualanex.com or toll free at 888-280-2043, Monday to Friday between the hours of 7 a.m. and 4 p.m. Central Standard Time.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-nationwide-vitrakvir-larotrectinib-oral-solution-20-mgml-due-presence

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.