66 Hudson Boulevard East
New York, NY 10001-2192

26th September 2024

IMPORTANT PRESCRIBING INFORMATION

Subject: Pfizer Voluntarily Withdraws OXBRYTA (voxelotor) from the Market for the Treatment of Sickle Cell Disease in Adults and Pediatric Patients 4 years of Age and Older.

Dear Health Care Provider,

The purpose of this letter is to inform you of the following:

Summary

- Newly generated clinical data evaluated by Pfizer and shared with the FDA indicates that the risk profile of OXBRYTA in people living with sickle cell disease exceeds the benefits observed in previously generated global research.
- Pfizer is voluntarily suspending distribution of OXBRYTA and removing the product from the market at this time.
- Pfizer is also discontinuing all ongoing OXBRYTA clinical studies and early access programs
- Patients should no longer be prescribed OXBRYTA. Prescribers should inform those living with sickle cell disease currently on treatment with OXBRYTA to stop treatment and discuss alternative treatment options with them.

Background

The FDA had previously granted accelerated approval for OXBRYTA for patients aged 12 years and older with sickle cell disease in 2019. In December 2021, the FDA granted accelerated approval for OXBRYTA to treat sickle cell disease in pediatric patients aged four up to 11 years.
OXBRYTA is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older. This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory trial(s).

Pfizer's decision is based on the totality of clinical data that now indicate the overall benefit of OXBRYTA no longer outweighs the risk in the approved sickle cell patient population. The data suggest an imbalance in vaso-occlusive crises and fatal events, which require further assessment. Consequently, Pfizer is voluntarily withdrawing the product from the market at this time. Pfizer is also discontinuing all ongoing OXBRYTA studies and early access programs.

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Prescriber Action

- Patients should no longer be prescribed OXBRYTA.
- Prescribers should inform people living with sickle cell disease currently on treatment with OXBRYTA to stop treatment and discuss alternative treatment options with them.
- Other healthcare professionals who receive any questions from patients currently prescribed OXBRYTA should direct these patients to their prescriber.
- Physicians should continue to monitor patients for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed. Complications when treatment is interrupted abruptly cannot be excluded, but neither efficacy nor a dose for gradual discontinuation have been established.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking OXBRYTA to Pfizer at 1-800-438-1985 (Option 1). You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch , or call 1-800-FDA-1088 (or 1-800-332-1088).
You may also contact our medical information department at 1-800-438-1985 (Option 3)

This letter is not intended as a complete description of the benefits and risks related to the use of OXBRYTA.

Please see Full Prescribing Information for Oxbryta.

For additional information, please call Pfizer on 1-800-438-1985 or www.pfizer.com

Sincerely,

Dr Ian Winburn
Chief Medical Affairs Officer Specialty Care,
Pfizer Inc.