August 4, 2026

Dear Sickle Cell Community,

Over the past two years*, Pfizer has comprehensively analyzed the totality of the final clinical trial, registry (real world), and post-marketing safety and efficacy data for Oxbryta (voxelotor) and provided this information to U.S. Food and Drug Administration (FDA) for review and continued discussion, with the goal of potentially making Oxbryta available again for people living with sickle cell.

Based on recent engagement with the FDA and their assessment of these data, it is clear that there is not a viable path to make Oxbryta available again in the U.S. We understand that this news is disappointing and we are deeply saddened by this outcome, especially given the significant unmet needs for people living with sickle cell.

Pfizer will stay present and actively engaged with the sickle cell community. This includes continuing our ongoing research efforts for osivelotor**, as we work to bring forward medicines for people living with sickle cell.

We also remain committed to transparency and will continue sharing voxelotor clinical data as it is published, including plain language summaries that make the findings accessible to sickle cell warriors, caregivers, and community organizations. We are confident that learnings acquired in the Oxbryta program will continue to inform future sickle cell research and innovation.

We are incredibly grateful to those in the sickle cell community for their support, time and engagement, including individuals living with sickle cell, caregivers, advocates, researchers, healthcare providers, and in particular those who participated in our clinical trials for Oxbryta.

Sincerely,

The Pfizer U.S. Sickle Cell Team

***Background:** *Pfizer withdrew Oxbryta from all markets globally and discontinued active voxelotor clinical trials in September 2024. This decision was based on the clinical trial and registry (real-world) data, which indicated that there were more vaso-occlusive crises (acute pain crises) and fatalities (deaths) for those taking Oxbryta. Since then, Pfizer has thoroughly reviewed the final Oxbryta data and shared it with regulators, including the U.S. Food and Drug Administration. The medicine remains off the market globally.*

***Osivelotor is an investigational medicine currently being evaluated in a Phase 2/3 clinical trial as a potential treatment for sickle cell disease. It has not received regulatory approval in any market.*