



**Dear Healthcare Professional Letter**

**IMPORTANT PRESCRIBING INFORMATION**

April 20, 2022

**Subject: Voluntary Withdrawal of Sale of UKONIQ® (umbralisib)**

Dear Healthcare Professional,

TG Therapeutics is advising healthcare professionals that it has decided to voluntarily withdraw UKONIQ® (umbralisib) 200 mg tablets from sale. The Company's decision is related to the Company's withdrawal of a pending application for FDA approval to market UKONIQ for the treatment of adult patients with chronic lymphocytic leukemia and small lymphocytic lymphoma in combination with ublituximab, an investigational anti-CD20 therapy.

No new patients should be treated with UKONIQ. For patients currently receiving UKONIQ, alternative treatment options and plans for transition to a different treatment should be discussed with the patient. Please note that in February 2022, the FDA issued a Drug Safety Communication regarding UKONIQ, informing healthcare professionals and patients of a potential increased risk of death in patients taking UKONIQ. FDA advised healthcare professionals and patients to consider the risks and benefits of continuing UKONIQ in the context of other available treatments. A copy of the Drug Safety Communication can be accessed here - <https://www.fda.gov/safety/medical-product-safety-information/ukoniq-umbralisib-drug-safety-communication-fda-investigating-possible-increased-risk-death-lymphoma>.

For those patients for whom there are no suitable alternative treatments available, who are benefiting from UKONIQ, and who wish to continue their treatment with the product following its withdrawal from sale, please contact the Company at 1-877-848-9462. The Company is currently considering potential approaches to working with healthcare professionals to make UKONIQ available for these patients.

We do not take this decision lightly and are grateful to the investigators and patients who helped to make UKONIQ available to those who have benefited from treatment.

**Action required by Healthcare Professionals**

- Do not begin treating any new patients with UKONIQ.
- Discuss alternative treatment options and plans for transition to a different treatment with patients receiving UKONIQ.



### **Reporting Adverse Events**

Healthcare professionals and patients are encouraged to report adverse events in patients taking UKONIQ to TG Therapeutics at 1-877-848-9462. You are also encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

You may contact our medical information department at 1-877-848-9462 if you have any questions about the information contained in this letter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Hari P. Miskin".

Hari P. Miskin, MS  
Chief Development Officer