What's Happening:

- Chimerix is a US-based biotech company, focused on oncology. ONC201 and ONC206 are investigational therapies that they are developing, and they are both currently in clinical trials (not yet approved by any regulatory body or commercialized). Chimerix isn't in any way affiliated with the third-party German supplier, which was making an unregulated, unapproved, counterfeit version of what they claimed to be ONC201 & ONC206.
- Bottom line, it looks like this third-party supplier may no longer providing this counterfeit drug to patients, and Chimerix is taking steps to make sure that patients who are in this situation and who may see clinical benefit from ONC201 could be eligible to apply for access through Chimerix's EAP that is available in the US and may be available early next year in certain European countries.
- Normally, the pathway for getting access to ONC201 is through clinical trials and that remains the critical path to properly evaluate the therapy with the goal of regulatory approval.
- Given the circumstances with the counterfeit supplier, patients who have been taking the counterfeit drugs would not historically qualify for ONC201 clinical trials. However, Chimerix is expanding the eligibility criteria for the various Chimerix ONC201 programs to accommodate some eligible patients including those who have been taking ONC201 sourced from a known counterfeit supplier prior to 31 Dec 2023, to help fill the gap caused by the counterfeit supplier.

Chimerix Expanded Access Program:

- Chimerix has already begun expanding its U.S. Expanded Access Program (EAP) to accommodate some eligible patients, including those who have been taking ONC201 sourced from a known counterfeit supplier prior to 31 Dec 2023. Chimerix's EAP offers monitored access to ONC201 under the care of an appropriately qualified physician.
- Until recently, Chimerix's EAP has only been available in the U.S. Now, Chimerix is establishing a Managed Access Program (MAP) in certain countries.
- Eligible patients outside of the US, including those who have been taking ONC201 sourced from a known counterfeit supplier prior to 31 Dec 2023, may be able to apply for Chimerix's ONC201 MAP.
    - The UK MAP and Australia are now live.
    - The German MAP is expected to be live in February.
    - Chimerix is also exploring a MAP in other countries (more details to come).
- This expected timing is based on the latest information Chimerix has. Of course, things could shift based on many factors.
- For patients outside of the U.S. who are eligible for the program but do not have enough supply to wait until the program opens in their home country, or for patients who don't live in a country where a MAP is currently planned, there are a few options:
    - Travel to the U.S. and enroll in the recently amended EAP under the treatment of a U.S. physician.
    - Travel to another country where a new MAP has opened and enroll in MAP under the treatment of a physician in that country.
- ONC201 is only available on EAP/MAP programs as a monotherapy administered once per week based on the evidence of safety and durable response that have been established in clinical trials.

Other ONC201 Programs:

- In addition to the global Phase 3 ACTION trial and EAP programs, Chimerix is also working with cooperative groups to evaluate ONC201 in clinical trials that enroll patients with H3 K27M-mutant

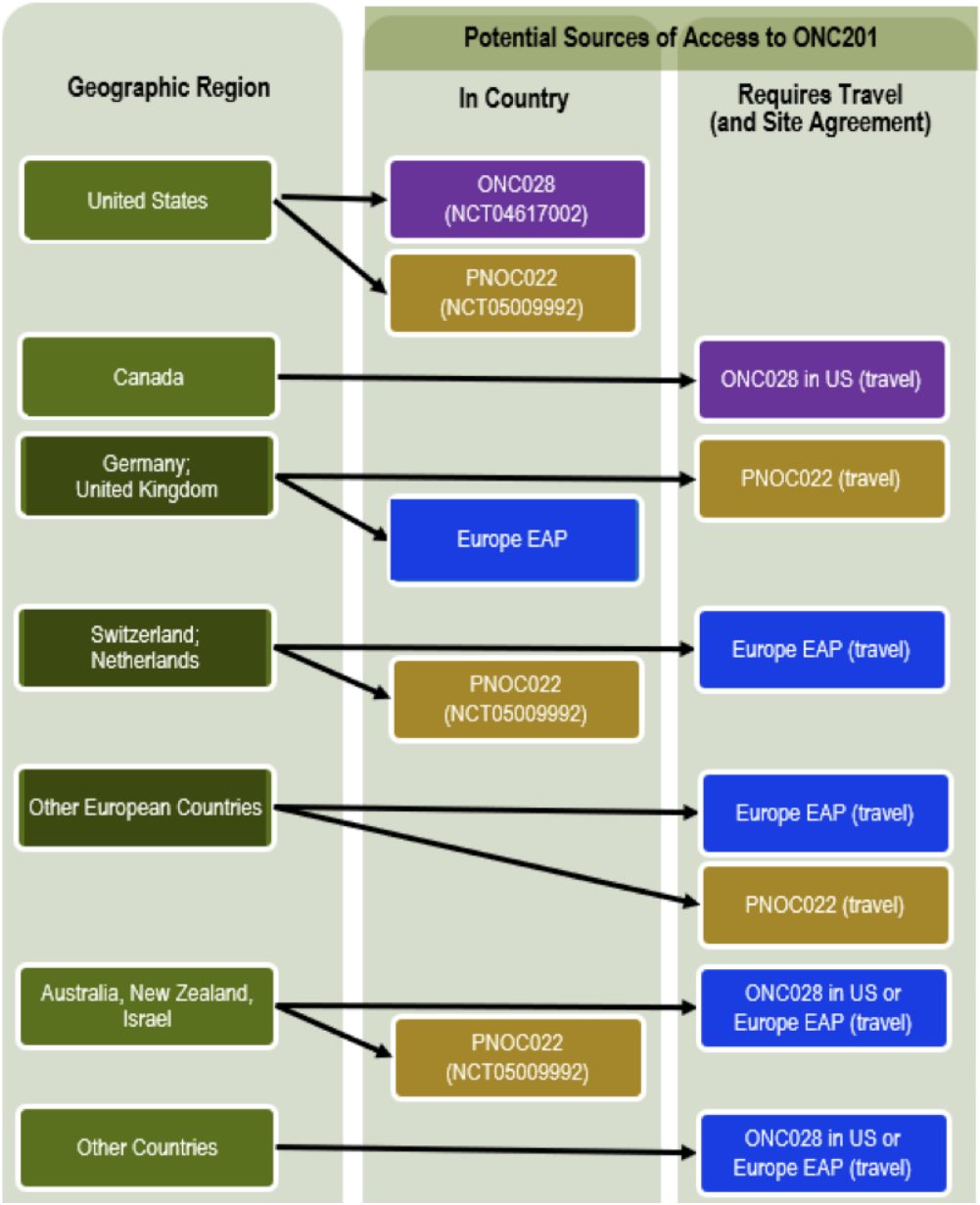
gliomas and/or midline gliomas. Similar to the recent eligibility adjustments to the ONC201 EAP/MAP, Chimerix is working with the Pediatric Neuro-Oncology Consortium (PNOC) to potentially expand the enrollment of the PNOC022 study to include patients who have used alternative source ONC201 prior to a certain date. Note that this study has historically been active in the U.S., Netherlands, Switzerland, Israel, New Zealand, and Australia. Note that this trial is not led by Chimerix, that adjustments to the study have not been finalized, and the expected timing of amendment has not yet been announced.

- Patients who do not have the H3 K27M mutation and/or midline gliomas would not qualify for EAP/MAP or the ongoing Phase 3 clinical trial, as currently, the data suggests benefit only in patients who have the H3K27M mutations with ONC201.
- ONC206 is currently not available for EAP. ONC206 is currently only in Phase 1 dose escalation trials (NIH and PNOC023) without an established recommended Phase 2 dose or schedule for ONC206.

Next Steps for Patients:

- If you are based in the UK or Australia and think you might be eligible for Managed Access, you should have your physician contact MedicineAccess@clinigengroup.com.
- For all other patients who think they might be eligible for Expanded Access, the best thing to do is to have your physician reach out to expandedaccess@chimerix.com. This email address is intended for communication with physicians only, so it's essential that your doctor be the one to reach out to evaluate eligibility.

The following flow chart may be used to help direct physicians and patients to a potential study or Expanded Access Program (EAP) in their country or region. Note: This chart does not include studies open for newly diagnosed patients who are naïve to ONC201.



Notes:

- ONC028 is open for enrollment and sites are listed on https://clinicaltrials.gov/study/NCT04617002
- MAP in UK and Australia are now open for requests.
- PNOC022 enrollment is temporarily paused pending a protocol amendment.
- The status and participating sites are listed on https://clinicaltrials.gov/study/NCT05009992
- Not shown in the flow chart:
- ACTION (ONC201-108) is open in multiple countries for enrollment of newly diagnosed patients https://clinicaltrials.gov/study/NCT05580562
- BIOMEDE 2.0 is open in France for enrollment of newly diagnosed patients (Eudra CT 2014-001929-32)