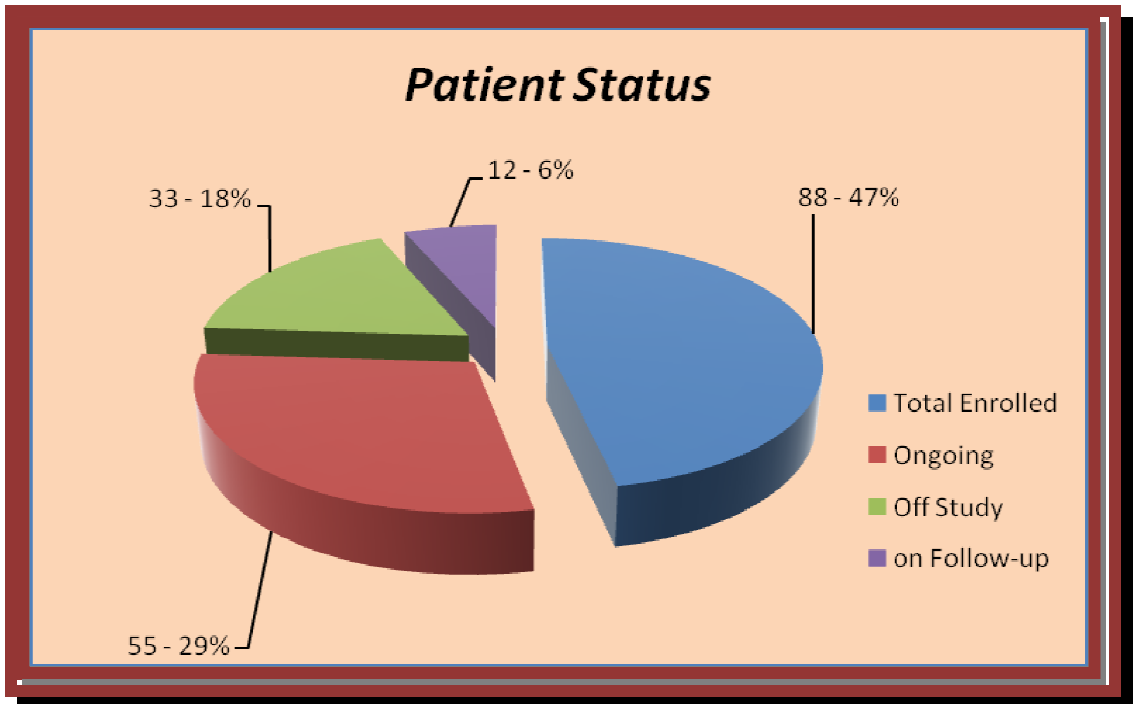




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## GEM017 continues with many patients still on study!

As the first week of January 55 of the 88 patients enrolled at European sites are still ongoing in the GEM017 trial. According to data received thus far, 12 patients have completed more than 6 cycles on the trial. Over 55 completed at least 3 cycles.



### e-CRF Data Entry Reminders

1. Data entry must be completed within 2 weeks of performed assessments.
2. Data should be entered into the eCRF for all screening failures.
3. All patients that are removed from active protocol therapy (complete 6 combination cycles) for reasons other than disease progression are required to have a CT scan to assess for disease progression every 6 weeks (unless other SCLC treatment has been administered).
4. Once there is documentation of disease progression the patient can then be followed every 3 months for survival.
5. GeminX performs interim data reviews and must have the most up to date information available.

## Outstanding Data Completion at Sites:



**Dr. István Albert**, the principle Investigator at *The Institute for Internal Medicine, Mátraháza State Hospital in Hungary* and his staff have shown great diligence in entering data into the eCRF system consistently, accurately and on time. Staff at this site who have been so valuable to the success of this study include:

**Research Nurse – Tibor Pirok**  
**Pharmacist – Péter Csonka**  
**Sub-Investigator – Dr. Magdolna Hovrath**

**Dr. Milan Antonic**, the principle investigator at *The Institute for Pulmonary diseases of Vojvodina in Serbia* and his staff have also been top producers of on time, consistent and accurate data. Our thanks goes out the staff who have helped keep up this standard:

**Sub-Investigator & Study Coordinator – Dr. Bojan Zaric**  
**Sub-Investigator – Dr. Branislav Perin**  
**Sub-Investigator – Dr. Jalena Stanic**  
**Sub-Investigator – Dr. Nensi Lalic**  
**Sub-Investigator – Dr. Milsos Stojanovic**  
**Research Nurse – Zdravica Stepanov**  
**Research Nurse – Marina Grahovac**



The teams from GeminX and Inc Research cannot stress enough the importance of accurate data collection and consistent data entry in to the eCRF system. GeminX performs regular data checks and uses this data to assess the treatment status and for the determination of future studies. Additionally GeminX will be submitting an abstract to ASCO for 2010. We extend our continued gratitude and thanks for your help in reaching our goals for this trial.

## Clarification Regarding Patient Withdrawal from Study

The GEM 017 SCLC protocol has as 2 different stages of patient study participation. The first stage is 6 cycles of combination therapy plus or minus PCI (depending on the patient's response to therapy). The second stage is the follow up period which is designed to address progression free survival and overall survival.

Those patients randomized to the treatment arm (obatoclax, carboplatin and etoposide) may continue on "ACTIVE" protocol therapy until documentation of disease progression. This would include 6 cycles of combination therapy plus or minus PCI and single agent obatoclax maintenance therapy. Patients randomized to the control arm (carboplatin and etoposide alone) are considered to be removed from "ACTIVE" protocol therapy at the completion of the 6 cycles of therapy plus or minus PCI, but remain on study in the follow up stage of the trial.

Below are some scenarios to illustrate how patient data should be recorded:

- A control patient completes 6 cycles of therapy and PCI. Patient is considered as completing the ACTIVE stage of the trial and the reason the patient discontinued the ACTIVE stage of the trial should be recorded as "Other-Patient completed 6 cycles of therapy". This patient is still considered to be on study however they are in the Follow up Stage of the trial and follow up data will be collected for progression and survival.
- A patient develops an AE or decides not to continue with any additional protocol therapy. The patient would be considered off ACTIVE protocol therapy and therefore the end of treatment panel needs to accurately reflect the reason. However, it is important to assess whether or not the patient continues to give their consent to remain on the follow up portion of the trial. If yes, then follow up data may continue to be collected for progression and survival.
- Patient decides to withdraw their consent from both the ACTIVE stage of the trial and the follow up stage of the trial. No more data need be collected on this patient and the end of treatment panel must accurately reflect this decision by entering "Patient refused treatment" or "Other" and specify "Patient withdrew consent".

### Close Out Visits (COV)

COVs will be scheduled throughout January and February at sites without patients or sites in which patients have come off study. The CRAs will need your help with the following:

1. All patient data to be entered into eCRF (also for screening failures).
2. Pending queries to be answered.
3. Study drug reconciliation documents to be completed.
4. Study drug to be returned and or destroyed as per instructions (including documentation).
5. Supplies (Vortex machine, infusion pumps, etc.) to be returned as per instructions.
6. All safety notifications to be documented.
7. Invoicing to be initiated (Data and current assessments must be entered for accurate invoicing).
8. All outstanding essential documentation to be complete.