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**Please Mail, FAX, or Email to Genzyme Corp.**
**Attn: Global Patient Safety & Risk Management**
**Fax: (617) 761-8506**
pharmacovigilancesafety@genzyme.com

**Campath Access/Distribution Program**

## ADVERSE EXPERIENCE REPORT

| Report Date: | Report Type: [•] Initial [ ] Follow-up | Reported to FDA: [•] Yes [ ] No | Drug/Biologic/Device: | |
|---|---|---|---|---|
| Reporter Name, Institution, Address: | | Patient Initials: | Indication: | |
| | | Age: | Date of Birth: | Dose/schedule or total daily dose: | Lot No.: |
| | | Gender: [•] Male [ ] Female | Height: [ ] cm [ ] in | Therapy Start Date: | Therapy Stop Date: [ ] continuing |
| Reporter's Telephone Number: | | Pregnant: [ ] Yes [ ] No [ ] NA | Weight: [ ] kg [ ] lb | Adverse Event Start Date: | Adverse Event Stop Date: [ ] Ongoing |
| Reporter's Fax Number: | | | | | |

Adverse Experience Description: Diagnosis (if known). Also describe signs, symptoms, severity, time course, relevant medical history, and relevant laboratory data. Include results of confirmatory procedures if any. Indicate any medication required to treat the event and the outcome. (Use additional paper if necessary.)

Adverse event term(s):

SAE Criteria: [ ] Death, date: Autopsy: [ ] Yes [ ] No
[ ] Life-threatening
[ ] Required or prolonged hospitalization
[ ] Persistent or significant disability/incapacity
[ ] Important medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes
[ ] Congenital anomaly
[ ] Intervention Required (devices only)

Severity: [ ] mild [ ] moderate [ ] severe
[ ] grade 1 [ ] grade 2 [ ] grade 3 [ ] grade 4 [ ] grade 5

Action taken regarding study drug/device:
[ ] Dose not changed
[ ] Drug/Device Interrupted. If checked:
Date Stopped: Date Restarted:
[ ] Drug/Device Withdrawn Stop Date:
[ ] Dose Increased. If checked, please explain:
[ ] Dose Reduced. If checked, please explain:
[ ] Not applicable. If checked, please explain:
[ ] Unknown

Relationship to to Study Drug/Device:
[ ] Not Related
[ ] Unlikely Related
[ ] Possibly Related
[ ] Related

Patient Outcome:
[ ] Recovered/Resolved
[ ] Recovered with Sequelae/Resolved with Sequelae
[ ] Recovering/Resolving
[ ] Not recovered/Not resolved
[ ] Unknown
[ ] Fatal

CONCOMITANT THERAPY (exclude treatment for SAE) (use additional paper if necessary)

| Medication: | Dose, Schedule or Total Daily Dose (units): | Start Date: | Stop Date: | Indication: |
|---|---|---|---|---|
| | | | [ ] ongoing | |
| | | | [ ] ongoing | |
| | | | [ ] ongoing | |
| | | | [ ] ongoing | |
| | | | [ ] ongoing | |

Reporter Name (Please Print) Date Reporter Signature