

FDA Actions



- ❖ **Notification of first event**
- ❖ **Identify studies under IND most similar to French Study**
- ❖ **3 trials ex vivo hematopoietic stem cells, retroviral vector, SCID**
- ❖ **BRMAC meeting October 10, 2002**
 - ❖ **<http://www.fda.gov/ohrms/dockets/ac/02/minutes/3897m1.doc>**

October 10 Conclusions



- ❖ **Because of great potential benefit, allow trials to proceed with new safeguards**
- ❖ **Revised informed consent, notify IRBs, implement clinical monitoring plan for early detection of leukemia/leukemia-like symptoms.**

2nd Event



- ❖ **Before SCID trials could begin, notified of 2nd event**
- ❖ **Reexamined all retroviral trial adverse event information, no evidence of vector caused leukemia**
- ❖ **As a precaution, enlarged scope of trials to ex vivo hematopoietic stem cells, retroviral vector, without regard to disease**
- ❖ **For life threatening diseases, consideration of restarting trials with implementation of requirements for first three trials.**
- ❖ **Original three trials to continue on hold pending BRMAC meeting February 28, 2003**