National AIDS Treatment Advocacy Project

Glaxo Wellcome announces 1592U89 Compassionate Use Program

Glaxo Wellcome announced on April 29, 1997 that a compassionate use program will be started for children, adults with severe dementia and for adults with advanced HIV in the United States, Europe and Australia. Drug for 2,500 individuals will be available for the entire program encompassing the three groups described above and the three geographical areas. It is anticipated that about 500 individuals will apply for the pediatrics and dementia programs. The remaining drug supply will be apportioned by the incidence of HIV in the three geographical areas.

The pediatrics program is expected to begin in June, and its preliminary entry criteria is viral load >100,000, CD4 <15%, and person has failed at least one NRTI (nucleoside such as AZT). For the AIDS Dementia Complex Program, the preliminary criteria are severe dementia (to be defined), diagnosed by a neurologist, and prior treatment with AZT.

For the adult program, a starting date in July is being planned. The preliminary entry criteria are viral load >50,000 copies/ml, CD4 <100, and failed two NRTIs and one protease inhibitor. Preliminary plans are that the program will run through geographically dispersed centers which will include the major cities for incidence of HIV-infection. They expect to be able to collect better data through this method. A broader expanded access program is being considered for early 1998.

Commentary--It is important to know that it is widely accepted that adding 1592U89 or any new drug to a current regimen which is failing is not usually the most effective way of using that drug. For example, if you are taking Crixivan and AZT/3TC and your viral load is 50,000, it is likely that regimen is failing, resistance is setting in, and merely adding 1592 or any one drug may not be very effective except possibly in the short term. It is likely that any benefit you receive from adding the new drug will be short lived due to the quick onset of resistance. The fullest possible suppression of viral load and durability of that suppression are the two major goals of therapy. It is generally accepted that because the only commercially available viral load test currently measure only as low as 200, 400 or 500 copies/ml (Roche PCR, Chiron bDNA), the goal of therapy is usually if possible to suppress viral load below those levels. Viral load tests measuring as low as 25 or 50 copies are in development and may be commercially available relatively soon. Once they are available suppressing viral load below 50 or 25 copies/ml will may be the new goals for therapy. However, there is a minority opinion that says it may be acceptable to maintain viral load in the vicinity of 20-30,000 copies. Researchers subscribing to this opinion are not convinced that it will be possible to fully suppress viral load indefinitely. By trying to do so, you may exhaust the limited number of the most potent drugs available. They are concerned that individuals may not be able to benefit from drugs developed in the future, because if your current regimen fails you may not be able to replace them with drugs of equal efficacy due to cross-resistance.

If an individual is 3TC resistant, there is preliminary data that you would still be able to receive full benefit from 1592, but the data available on this subject is still preliminary. If you are ddI resistant, preliminary data indicates you ought to be fully responsive to 1592. Some individuals who have extensive resistance to 3TC and ddI, may be less responsive to 1592. Although, enough research to adequately answer these questions now has not yet been done, eventually it is anticipated that we will have adequate data to answer these questions. Making good treatment decisions about how to best use 1592 for yourself should be more likely after there is more certainty regarding the answers to these questions, which should be available after the anticipated date of FDA approval about one year from now.

If you want to participate in this program, more information will be provided in the near future by Glaxo Wellcome directly to the public or through your doctor. NATAP will do its best to supplement this information either through our web site or by direct mailing to organizations and individuals throughout the New York City area, and to our readers elsewhere.