



Liège, July 27, 2011

Dear Professor, dear Doctor,

The impact and difficulties of the unavailability of Valcyte in daily practice in hematological malignancies is significant. There is an important need for an oral formulation especially for the preemptive treatment of CMV reactivation in bone marrow transplantation patients.

Therefore **Roche will place Valcyte samples at patients' disposal** (62 boxes in 2011, 126 boxes in 2012). The program is called "Valcyte Medical Supply".

The BHS has been asked to mediate in getting the limited Valcyte supplies to patients who need it most. A **BHS decision committee** has been created and consists of Prof J. Maertens, Dr X. Poiré and Dr P. Zachée. **X. Poiré will act as the coordinator** of the committee and maintain an Excel file with the approval status of all requests.

A **specific request form** has been developed for this purpose. You can access this form on the BHS website through the following link: www.bhs.be.

The inclusion criteria are (all criteria must be met):

- Allogeneic stem cell transplantation
- or
Treatment with Alemtuzumab
- Age \geq 16 yrs
- 2nd or later episode of asymptomatic CMV reactivation (patient had \geq 1 documented previous episode of CMV reactivation)
- 2 consecutive positive CMV viral loads within 1 week $>$ 1000 copies/ml
- **No** symptom of CMV disease:
- Patient not hospitalized
- ANC $>$ 500/ μ l (0.5 x 10⁹/L)
- Able to take oral medication
- No active gastrointestinal GVHD

The practical procedure will be as follows:

- The requesting physician fills out the "Valcyte Medical Supply" form with all the needed information.
- The request form is sent to the BHS decision committee by E-mail or by fax.
- Only requests for patients who meet the inclusion criteria mentioned in the form will be considered for approval.
- The requests will be reviewed within 5 working days and should be approved by at least 2 members of the BHS decision committee. Members of the BHS decision committee cannot approve their own requests. In case of no response within 5 working days, the coordinator may take the final decision alone.
- Once the BHS decision committee has approved the request, the requesting physician will be notified by fax (tick box on the request form). A patient code will be attributed.
- The requesting physician will then fax to Roche :
 - The request form approved by the BHS decision committee.
 - A signed and stamped prescription for 1 box of Valcyte, mentioning the patient code.
- Roche will send the samples to the pharmacist of the hospital.

Only 1 box of Valcyte will be sent for any patient with an episode of CMV reactivation, covering 2 weeks at full adult dose (900 mg bid) or 4 weeks at half-dose (450 mg bid). It is up to the physician to decide on when and how to use Valcyte in sequence or in combination with ganciclovir. However, **another request can be sent for the same patient if he/she presents a later episode** of CMV reactivation at least 2 months after the first one for which he/she received Valcyte through this program.

There will be a maximum of 8 boxes / physician / year.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Yves Bequin', with a long, sweeping underline that extends to the right.

Prof. Dr. Yves Bequin
President of the BHS