Working Group Molecular-Pathology

Meeting	**Wednesday 27 May 2008**, UZ BRUSSEL
Present	Mark Kockx (Chairman; ZNA/AZ Middelheim), Peter In't Veld (Secretary; UZ Brussel), Brigitte Maes (Virga Jesse Ziekenhuis, Hasselt), Pieter Demetter (ULB- Dominique Begon (ULG Sart-Tilman), Laurence de Leval (ULG, Sart-Tilman), Roberto Salgado (ZNA/AZ Middelheim), Patrick Pauwels (UZ Gent), Louis Thienpont (OLVG Aalst), Herwig Alaerts (UZ Leuven), Anne Hoorens (UZ Brussel), Christine Sempoux (UCL- St Luc),
Excused	Gert De Hertogh (UZ Leuven), Tania Roskams (UZ Leuven), Sabine Tejpar (UZ Leuven), Miriam Marichal (UZ Brussel), ErasmePhilippe Delvenne (ULG), Els Dequeker (UZ Leuv

1. Minutes of the previous meeting of 27 Febr 2008
Laurence de Leval was added to the list of colleagues who were excused for the meeting.

2. Art 33bis
The working group has proposed on April 14 to the INAMI/RIZIV (dr Genevieve Haucotte) that a new article should be added to the art33bis nomenclature " 588xxx-5888yyy detection of KRAS mutations in the context of selection of therapy for colorectal carcinoma in the diagnostic phase of investigation (maximum 1) (diagnostic rule 1) B8000". The proposal was discussed by the TGR in their meeting of May 27.

It has recently become clear that reïmbursement under art 33bis will only be possible for Centers that have been formally approved by the WIV. Article 22 of 28 July 2003 §18 implies that reïmbursement will only start after the RIZIV/INAMI has been informed by the Ministry of Health (WIV) that testing centers meet the quality criteria mentioned in art 33bis and 24bis. There is thus a serious legal problem for reimbursement. Until this is resolved, all testing performed from August 2007 until the formal recognition of the Center by the WIV will not be reïmbursed.

3. KRAS mutation testing guidelines
During the working group meeting of 27 Febr a task force was formed to write a set of KRAS mutation testing guidelines. The task force is chaired by Sabine Tejpar (UZ Leuven). A draft guideline was made available during the meeting and a preliminary discussion was held. The draft guideline is attached to the current meeting minutes and members of the working group are invited to mail their comments to Sabine Tejpar (sabine.tejpar@uz.kuleuven.ac.be), kockx@histogenex.com and intveld@vub.ac.be **before June 18**.

The following initial comments were made during the meeting and were adopted by the members:
- KRAS mutation testing should be performed in response to a specific request from the oncologist (ie "on demand" testing rather than "up front" testing).
- The pathologist has a central role in the process of mutation testing as is correctly underlined in the guidelines. However, most Centers feel that the peripheral pathologist should always send in the paraffin block and should not send in slides as suggested as an option in the guideline. The testing center will be responsible for determining the % tumor cells and the tumor area and not the requesting pathologist.
- Method validation: Correctness and Gold standard should perhaps be replaced by Accuracy.
- A turn around time of 10 working days for the testing lab is considered realistic.
-The 95% success rate for DNA extraction and testing is deemed (too) ambitious as the Centers will often have no control over the preanalytical phase.
- The paragraph on reïmbursement should not be an integral part of the guidelines.

AMGEN is reported to be compiling a (long) list of Belgian KRAS testing centers for distribution to oncologists. The secretary of the working group will contact AMGEN to stress that such a list may be premature as in the near future only centers accredited under art 33bis will be eligible.