

Content

- 1 **BGDO By-laws**
- 2 **DNET**
- 3 **ECHO trial**
- 4 **Magnet trial**
- 5 **PETACC-6**
- 6 **PETACC 8**
- 7 **LAP 07**
- 8 **PePiTA trial**
- 9 **Recognition in Oncology**
- 10 **Announcement**

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Dear Members, Colleagues and Friends,

***THE BGDO story: 6 years away from launch...
we will continue to grow up with a new board.***

The BGDO was created in 2003 by a small group of motivated individuals who were convincing that digestive oncology had an exciting and promising outcome.

I had the privilege to be elected as the first chairman (2003 – 2006) and to be renewed in 2006 until now. This year, after our elections, my successor will take the lead of the Group and continue to promote and develop our activities.

Since 2003, I am very proud to have contributed with all the board members to put the BGDO in a well-visible place in Belgium but also in Europe and to give a valuable legitimacy to digestive oncology.

Since 2003, we have achieved a lot of projects and activities in research, training, education and support to cancer care organization in Belgium. The list is long but I would emphasize our annual meeting in January attended by more and more people and now co-organized as a joint meeting with the BSSO; our increasing participation at the Belgian Week of Gastroenterology and our recognition now as one of the seven co-organizing societies in 2010, our participations to European trials like PETACC 8 (adjuvant colon cancer), PETACC 6 (adjuvant rectal cancer), LAP07 (chemoradiation in pancreatic cancer), the development of investigator-initiated trials like MAGNET, ECHO and newly PEPITA and the DNET registry which will be updated soon.

Our contribution was also appreciable in the Plan Cancer/Kanker plan, in the elaboration of the screening campaign in CRC in both communities and last but not least in the achievement of the specific criteria dealing with the qualification in Digestive Oncology that will be available in the beginning of 2010 as promised by the Ministry of Health....

After six years of evolution and progress, I am confident in our active Group and according to our updated bylaws, a new board will be established after election of 6 new members and continue their task.

Since October 2009, we can now rely on the expertise in clinical research of Mrs Joëlle DICK who was engaged for managing our clinical trials and who will contribute to evaluate the quality of our research.

I will finish my mandate by giving my warm thanks to all the board members and officers who have achieved a tremendous work since 6 years, in an ever fair and constructive ambiance.

I also thank the pharmaceutical companies for their active support and partnership since we have started the BGDO story.

And last but not least, I just want to stress that all these achievements would have not been possible without Mrs Anne-Sophie WIRTZ who has joined us in 2004; on behalf of all the board, I warmly thank her for her generosity and excellent contribution.

Best wishes for 2010!

*Jean-Luc Van Laethem
Chairman*

1 BGDO by-laws

The board decided to change the by-laws to improve the efficacy of the board, to guarantee the representation of the two linguistic regions and academic/non-academic hospitals and to prevent discussions after elections.

The major changes are:

- The duration of the mandate of board members will be 6 years.
- The president, vice-president, secretary and treasurer are elected by the board for three years and can be re-elected.
- Every 3 years 50 % of the members of the board vacate their seat. Members who withdrawn, can be re-elected.
- A maximum of two members of the same hospital or same university in the board.

As a unique transitional measure with the first elections after the adjustment, the board decided also that this time the following 6 members will remain in the new board for 3 years: Alain Hendlisz, Ghislain Houbiers, Jos Janssens, Marc Peeters, Eric Van Cutsem and Jean-Luc Van Laethem.

Every member of the BGDO can vote for maximum 6 names. It's important to note that the election of candidates is based on the ballot count but also on the guaranteed representation system, according to our by-laws.

2 DNET



As you will hear during the afternoon session of today's program, the **DNET registry** was launched in spring 2005, nearly 5 years from now. Currently, 164 patients are included, 23 more than in December 2008. As this is less than expected, we look for solutions to help you filling new and existing cases, going back to JUNE 2004. The BGDO board has engaged **Joëlle Dick** (joelledick.bgdo@gmail.com) as clinical trial manager. Joëlle has been trained to the registry, but her role will be to help you, not to replace your work! We are evaluating the possibility of a financial help for each case included, but also for follow-up, as we believe it is also very important. This is crucial as there is a will to participate to the European NET registry, supported by the ENETS.

3 ECHO Trial

We are very proud to announce that we have been able to include **all 43 patients scheduled** in the **ECHO** study, studying the efficacy of gemcitabine and cetuximab in advanced cholangiocarcinoma, excluding gallbladder cancer. This achievement is a clear success, as 38 patients have been included in 12 months! Hopefully we will show you the results of the study, when mature data will be available. We believe that we could be more ambitious in terms of patient recruitment number. As you are probably aware of, a recently presented phase III showed superiority of the combination gemcitabine-cisplatin over gemcitabine alone. In line with these results, we plan to design and propose a randomized phase II, comparing Gemcis+/- drug. You will hear about this project in the coming months.

4 Magnet Trial

90 subjects enrolled till now ~ Still 70 subjects to include !

Reimbursement Criteria for Cetuximab were expanded.

Before the summer 2009 Cetuximab was only reimbursed for the third line therapy in metastatic colorectal cancer. As Cetuximab is reimbursed now in all therapy lines for patients suffering of metastatic colorectal cancer, all these patients receiving Cetuximab in combination with or without another chemotherapy can be included in the Magnet trial.

5 PETACC-6

The BGDO participates as one of the European groups to the PETACC (Pan European Trials Adjuvant Colon Cancer)-6 trial. This trial is coordinated by the EORTC.

In the PETACC-6 trial patients with locally advanced non-metastatic rectal cancer are randomized between 2 preoperative regimens of chemoradiotherapy: capecitabine plus radiotherapy or capecitabine/oxaliplatin and radiotherapy. Patients receive an irradiation of 45 + 5.4 Gy in fractions of 1.8 Gy. The preoperative chemoradiotherapy is followed approximately 6 weeks later by optimal surgery: Total Mesorectal Excision. After the operation a postoperative chemotherapy is continued with either capecitabine or capecitabine plus oxaliplatin for 6 cycles.

On January 4, 121 patients were included internationally of which 41 in Belgium. BGDO centers that have recruited until now patients are St Elisabeth Namur, St Elisabeth Turnhout, UZ Gasthuisberg/Leuven, St Augustinus Antwerpen and Mont Godinne. The total sample size for the trial is 1090 patients.

6 PETACC-8



Three years ago the BGDO has joined the PETACC structure, which is committed to design large intergroup phase III studies through Europe; the BGDO is now recognized as the national cooperative group in this structure and is participating to the large PETACC 8 trial, assessing the value of adding cetuximab to FOLFOX 4 in stage III colon cancer.

26 centres have been opened in Belgium; the trial is promoted by the French group FFCD. Quintiles, as CRO is monitoring the study.

After the recent publication of the KRAS data and the role of KRAS status in predicting anti EGFR therapy resistance, the trial was amended in September 2008 to restrict the recruitment on KRAS wild type colon cancer.

Above the 2100 patients initially planned in the first design of the trial, 450 additional KRAS WT stage III colon cancer have been enrolled in order to recruit a total of +/- 1400 KRAS WT tumors and to demonstrate a benefit of adjuvant therapy in this selected population.

The study recruitment has been stopped in November 2009 after 2564 patients have been included in the trial. In Belgium 206 patients were randomized.

7 LAP 07

A large intergroup study has been launched in the setting of pancreatic cancer (locally advanced) aiming to recruit 800 patients in France (GERCOR), Germany (AIO), Australia and Belgium (BGDO); US and Canadian groups have been also contacted.

The study is designed to answer the place of radiochemotherapy in LAD after induction with chemotherapy (gemcitabine +/- Tarceva). The study is now open in Belgium and 12 patients were enrolled (+/- 150 in France).

8 PePiTA Trial

The **PePiTA** trial is **now open for patient recruitment in Belgium**. (*Preoperative chemosensitivity testing as Predictor of Treatment benefit in Adjuvant stage III colon cancer*)

Colorectal cancer (CRC) is a major public health problem hitting over 7500 patients per year in Belgium. Despite intended curative surgery, the risk of recurrence is significantly high, even with limited disease.

Adjuvant chemotherapy in stage III colon cancer, is associated with a significant improvement in overall survival (OS) compared to surgery alone. Current standard of care is FOLFOX since publication of the Mosaic trial in 2005.

PEPITA trial is a **Belgian multicenter trial**, sponsored by a **National Cancer Plan** grant, which runs under the auspices of the BGDO.

Its main aim is to assess validity of FDG-PET changes in tumoral FDG uptake after 1 course of preoperative chemotherapy as surrogate for adjuvant therapy outcome, measured by 3 years Disease Free Survival.

An analyze of the preoperative chemosensitivity testing cost-effectiveness and translational substudies are foreseen, including

- a) CTC (circulating tumor cells)
- b) SNP's Translational research on toxicity and drug target related genes
- c) Creation of an academic frozen tumor bank for future translational studies.

A central Core Imaging platform (MicoLAB) has been created to harmonize and analyse the FDG-PET data.

9 Recognition in Oncology

Different meetings have been planned at the Ministry with representatives of groups and societies. The specific legal texts on the different criteria regarding gastroenterology and pneumology are pending and were promised by the Cabinet for beginning of 2010; discussions are ongoing for other specialities. Since the texts are not yet ready, a new "arreté" was published in November , prolonging the transitory period until 30 June 2010 (4 years of practice in oncology) and the new deadline for application is now 31 December 2010. We will give information to our members as soon as we get them from the Cabinet or from the "Monitor".

10 Info Congress 2010

- ASCO GI congress Orlando, January 22-24 www.gicasymposium.org
- International Congress on Anti-Cancer treatment Paris, February 1-5 www.icact.com
- Belgian Week of Gastroenterology Antwerp, March 4-6, www.belgianweek.be
- ASCO Chicago, June 4-8 www.asco.org
- World Congress on GI Oncology Barcelona, June 30-July 3 www.worldgicancer.com
- ESMO Congress Milan, October 8-12 www.esmo.org

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