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The joint ECCO 15–34th ESMO Multidisciplinary Congress took place in Berlin, 20–24 September, 2009. *Helen Saul* and *Robert Day-Webb* report

Launch of European Academy of Cancer Sciences

The new European Academy of Cancer Sciences will offer evidence-based advice to European politicians and policy-makers, its first President, Professor Alexander Eggermont (Erasmus University, the Netherlands), said at the joint ECCO 15–34th ESMO Multidisciplinary Congress (Berlin, 20–24 September, 2009).

Launching the Academy at the first Presidential session, Professor Eggermont said, 'We hope it will become an important reference point for policy-makers and professionals in the field of oncology research and oncology care, where they can go to ask questions and receive suggestions and advice.'

Speaking later to *EJC*, Professor Eggermont, who is also the outgoing President of ECCO, said that politicians were confused by the messages they were receiving from the oncology community. 'They have been dependent on sound-bites from individual interest groups; sound-bites that were often perpendicular to one another. Too much of what they heard was emotionally-based advice from lobby groups. Not surprisingly, politicians have found the oncology world unstructured and difficult to understand.

Photo: franknuerenberger.de

Professor Alexander Eggermont

'The creation of the European Academy of Cancer Sciences fits in perfectly with ECCO's mission to 'structure the oncology community' and communicate with one voice on the big issues that concern us all. It will be able to provide evidence-based and scientifically sound advice on the 'common denominator' problems,' he said.

The Academy follows on naturally from the formation of ECCO from FECS, he said. Where FECS had become inward-looking, concentrating on professional issues affecting its six member societies, ECCO, formed 2 years ago, is a broader, more dynamic organisation. Membership was extended to include all stakeholders such as EORTC, ESO, organ-based societies such as EAU (European Association of Urology) and EANO (European Association of Neurooncology) etc. Cancer leagues and patient platforms also joined and the whole structure was opened up so that anyone could nominate a leader in their field for election on to the Board.

'Once the organisation was clearly defined as one that provided a structure for the oncology community, the idea grew of creating a foundation to issue the type of advice that Governments need. It had to come from an authoritative and independent body,' Professor Eggermont said.

To that end the Academy has been created under the auspices of ECCO and with the ECCO Oncopolicy Committee as a multidisciplinary interface. Questions brought by politicians or policy makers will go to ECCO's policy committee, which will in turn set up a working party or ad hoc committee comprised of Academy members.

Julio Celis, director of the Danish Cancer Society and chair of ECCO's policy committee, was instrumental in drawing up plans for the Academy, and it started with an initial group of 30, chosen on the basis of their experience and reputation. They included Nobel prize winners Professor Harald zur Hausen (who is now vice-President of the Academy), Professor Sir Paul Nurse, Professor Umberto Veronesi and epidemiologist Professor Sir Richard Peto.

POLITICIANS HAVE FOUND THE ONCOLOGY WORLD UNSTRUCTURED AND DIFFICULT TO UNDERSTAND

The initial group voted for further members and the founding group now stands at 115. It is expected to expand to include a further 50 members per year, up to an eventual total of 500 or 600. New names will come through current Academy members, and national Academies will be asked to putforward candidates, so that all nations and disciplines will be represented. All will be expected to have outstanding track

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ECCO 15–34th ESMO Multidisciplinary Congress

Launch of European Academy

(*continued from page 1*)

records in their field and membership will be lifelong.

The Academy's work has already started. Various groups will be working on a series of white papers on, for example, how cancer research can be structured to avoid fragmentation and duplication. 'The Academy will be able to make a number of suggestions,' Professor Eggermont said.

Questions on cancer care will be addressed, such as how to set priorities in national cancer plans. 'The axiom is that one model does not fit all. No country is the same as another, and different countries will have different priorities in optimising quality of oncology care.'

Mobility of patients and researchers across Europe could be another topic addressed, as could the approaches needed to ensure optimal care for patients with rare cancers.

To date, ECCO has financed the creation of the virtual body, but as it grows, additional resources will be needed. 'I'm optimistic this can be achieved,' said Professor Eggermont.

At the launch of the EU's Partnership against cancer programme, EC Health Commissioner Androulla Vassiliou and Research Commissioner Janez Potoènik said that they supported the creation of the Academy and would support and possibly attend the Academy's first forum, due to take place in Brussels in September, 2010.

'The Partnership launch was well-attended by policy makers from Brussels, directors of departments of science and health from various countries and patient advocacy groups. They were enthusiastic about the Academy, asking why it hadn't been created before,' said Professor Eggermont. 'This remark is probably the best indication that it's a good idea. People immediately recognised the need for it. It was very heartening, and suggested that, if it's managed well, the Academy will come to play an important role in cancer in Europe.'

HS

Regional hyperthermia in soft-tissue sarcoma

Patients with high-risk soft-tissue sarcomas who received chemotherapy plus regional hyperthermia were 30% more likely to be alive and disease free almost 3 years after starting treatment compared to patients receiving chemotherapy alone, according to results from the EORTC-ESHO intergroup trial.

The study, which found that the addition of the innovative heat technique more than doubled the proportion of patients whose tumours responded to chemotherapy without increasing toxicity, is the first to show that any treatment other than surgery followed by radiation can prolong survival of this type of patient.

'THIS IS THE FIRST CLEAR EVIDENCE THAT TARGETED HEAT THERAPY ADDS TO CHEMOTHERAPY'

'These findings provide a new standard treatment option and we believe they are likely to change the way many specialists treat these tumours,' study leader Professor Rolf Issels (University of Munich, Germany) told a Presidential session.

The phase III study included 341 patients with high-risk soft-tissue sarcoma who were randomly assigned to chemotherapy (etoposide 250 mg/m^2, ifosamide 6 g/m^2, adriamycin 50 mg/m^2) with or without regional hyperthermia.

The heat technique, given before and after surgery and radiotherapy, uses focused electromagnetic energy to warm the tissue in and around the tumour to between 40 and 43 °C. The heat is intended to kill cancer cells but also to make cancer cells more sensitive and improve blood flow, thereby enhancing the efficacy of the chemotherapy.

'The patients receiving the targeted heat therapy fared better on all outcome measurements,' said Professor Issels.

Almost 3 years after starting treatment, those who received the heat therapy were 42% less likely to experience a recurrence of their cancer at the same site, or to die, than those on chemotherapy alone. They survived an estimated 120 months before local progression of their disease, compared with an estimated 75 months. Similarly, the average length of time that patients remained disease free was 32 months in the heat treatment group, compared with 18 months among those receiving chemotherapy alone, which is an improvement of 30%.

The improvement in overall survival was not statistically significant when all patients were analysed, but in the 269 patients who completed the full treatment, those who received the heat treatment were 44% less likely to die during follow-up than those assigned to chemotherapy alone.

At 2 years, 76% of patients in the regional hyperthermia group were alive without local progression compared to 61% in the chemotherapy alone group. Tumour shrinkage occurred in 28.8% of patients assigned to the combination therapy compared to 12.7% in the chemotherapy only patients. In addition, tumour growth was 6.8% in the heat therapy group compared to 20% in those assigned to chemotherapy alone.

'The implications of these findings are far-reaching,' said Professor Issels. 'This is the first clear evidence that targeted heat therapy adds to chemotherapy. We expect our findings will encourage other researchers to test the approach in other locally advanced cancers. Targeted heat therapy has already shown promise in recurrent breast and locally advanced cervical cancer in combination with radiation, and studies combining it with chemotherapy in other localised tumours such as those in the pancreas and rectum are ongoing.'

Outstanding questions include whether targeted heat therapy can play a role in stimulating the immune system to more effectively attack cancer, Professor Issels said, adding that studies of heat shock protein therapy indicate that they may activate the immune system against the disease.

R D-W

(*EJC Supplements 2009 7:3 2 #1LBA*).

ECCO 15–34th ESMO Multidisciplinary Congress

Trastuzumab 'provides survival benefit in gastric cancer'

The drug trastuzumab (Herceptin), when added to standard chemotherapy, showed 'an unprecedented survival benefit' for patients whose tumours exhibited a high level of HER2, according to Professor Eric Van Cutsem (University Hospital Gasthuisberg, Leuven, Belgium), principle investigator of the ToGA trial.

Presenting results to a Presidential session (*Best Abstract #7*), Professor Van Cutsem said the phase III results showed 'a significant and clinically meaningful improvement in overall survival and all secondary efficacy parameters.' Addition of trastuzumab to standard chemotherapy is a novel, effective and well tolerated treatment that sets a new standard of care for patients with advanced gastric cancer and HER2 over-expression, he said.

The trial randomised 584 patients with a locally advanced, recurrent or metastatic HER2-positive gastric cancer to receive chemotherapy (cisplatin and either 5-fluorouracil or capecitabine) plus trastuzumab or chemotherapy alone.

Patients who received trastuzumab plus chemotherapy lived 13.8 months, compared with 11.1 months for those who received chemotherapy alone. The treatment was generally well tolerated with no unexpected side effects in the trastuzumab group.

'THIS REINFORCES THE NEED FOR HER2 TESTING OF ALL ADVANCED GASTRIC CANCERS'

'It is now clearly proven that trastuzumab prolongs the lives of patients suffering from HER2-positive gastric cancer. As an investigator on this study and a treating physician, it is very rewarding to see a new effective treatment option emerging,' said Professor Van Cutsem. 'The results of the ToGA study reinforce the need for early and accurate HER2 testing of all advanced gastric cancer patients.'

Photo: franknuerenberger.de

Professor Eric Van Cutsem

R D-W

(EJC Supplements 2009 7:3 7 #7BA)

Aspirin 'cuts colorectal cancer risk'

A daily dose of aspirin may protect against colorectal cancer in individuals with Lynch Syndrome, according to follow-up data from the international chemoprevention study, CAPP2.

Lead author Professor John Burn (Newcastle University, Newcastle upon Tyne, UK) told the meeting that the protection continued for years after the aspirin was discontinued. 'This is a statistically significant result and we are delighted – all the more so because we stopped giving the aspirin after 4 years, yet the effect is continuing, and is directly correlated with the duration of aspirin use on the trial.'

Professor John Burn

Lynch Syndrome, or hereditary non-polyposis colorectal cancer, accounts for around 5% of all colon cancers.

The trial involved 1071 carriers of the Lynch Syndrome mutation in 42 centres worldwide. Participants were randomised to receive a daily dose of 600 mg aspirin and/or 30 g Novelose, a resistant starch that escapes digestion in the small intestine.

The first results were disappointing, Professor Burn said. At an average of 29 months after randomisation, there was no evidence of the benefits of aspirin in the high-risk population studied. However, at around 4 years after randomisation, there was a divergence in the incidence of cancers between the aspirin and placebo groups. To date, there have been 6 colon cancers in the aspirin group, versus 16 in the placebo group. There was also a reduction in endometrial cancer with aspirin.

Eleven patients in the aspirin group had notable gastro-intestinal bleeding or ulcers as opposed to nine in the placebo group. Individuals taking aspirin also had a lower rate of cardiovascular events.

The mechanism by which aspirin protects against cancer has yet to be elucidated, but the researchers believe that cancer stem cells are involved: 'We do not think that the mechanisms discussed to date are likely to provide an explanation,' said Professor Burn. 'For example, the inflammatory enzyme COX2 is over-expressed in early cancer, but our results suggest an effect that predates the cancer, and may even predate the adenoma which precedes it.'

'We believe that aspirin may have an effect on the survival of aberrant stem cells in the colon. These cancer stem cells are normally resistant to chemotherapy, but if a stem cell mutates but does not reveal its potential until an adenoma is formed, and if aspirin reduced the chances of such cells surviving, this would explain our results.'

The team is intending to undertake a further study to see whether a smaller dose of aspirin would have the same beneficial effect.

R D-W

(EJC Supplements 2009 7:2 320 #6000)

ECCO 15–34th ESMO Multidisciplinary Congress

Sorafenib 'active in advanced breast cancer'

Sorafenib, in combination with chemotherapy, improved progression-free survival by 74% in patients with advanced breast cancer, compared to chemotherapy alone, a phase II study found.

Principal investigator Professor José Baselga (Vall d'Hebron University Hospital, Barcelona, Spain) presented the results at a Presidential session: 'This is a very positive study and the magnitude of the benefit is such that it suggests that this agent will be an important addition to our therapeutic armoury in breast cancer,' he said.

In the study, 229 patients with locally advanced or metastatic breast cancer were randomised to receive capecitabine and a placebo, or capecitabine and sorafenib.

Photo: frankmuerenberger.de

Professor Jose Baselga

Results showed that the average progression-free survival was 6.4 months for women on capecitabine and sorafenib compared to 4.1 months for women taking placebo, a statistically significant result. The researchers said that it was too early for data on overall survival to be available. Overall, treatment with sorafenib plus capecitabine was tolerable and resulted in no new side effects.

'This trial is the first of a series of randomised phase II studies with sorafenib that are currently underway in breast cancer. Based on our results, we believe that the drug shows considerable promise for the treatment of the disease,' said Professor Baselga.

R D-W

(*EJC Supplements 2009 7:3 3 #3LBA*)

Divorce rate 'not affected' by childhood cancer

Parents with a child diagnosed with cancer are no more likely to divorce than others, Dr Astri Syse (Cancer Registry of Norway, Oslo, Norway) said.

She presented results of a registry based study, which included the entire Norwegian married population aged 17–69, with children under the age of 20 between 1974 and 2001. Divorce rates for the 4524 couples with a child with cancer were compared to those of otherwise similar couples.

'Contrary to existing myths, cancer in a child is not associated with an increase in parental divorce risk,' Dr Syse said.

Professor Kathy Pritchard-Jones (London, UK) selected the talk for presentation at a highlights session: 'We are all aware of the incredible stress placed on the family when a child is diagnosed with a life-threatening disease like cancer. My clinical impression has always been that families often do split up as a result of this stress. The finding was surprising.'

She added, 'In Norway, when a child is diagnosed with cancer the parents are routinely offered psychological support and this may be a partial explanation for these findings.'

One exception to the general finding was among highly educated women, who were more likely to divorce. Dr Syse said this could relate to these mothers' wish to work outside the home, which may be difficult given an increased care burden at home. She said further studies 'are clearly warranted to understand the background for the observed increase in divorce risk for these couples.'

HS

(*EJC Supplements 2009 7:2 4104*)

Sunitinib in pancreatic cancer...

Treatment with the tyrosine kinase inhibitor sunitinib significantly prolonged progression-free survival in patients with progressive well-differentiated pancreatic islet cell tumours, Dr Eric Raymond (Hospital Beaujon, Clichy) told the meeting.

The multinational phase III trial (NCT00428597), comparing sunitinib with placebo, was stopped early after a planned review by a data monitoring committee (DMC) in February 2009 recommended that all patients should be offered sunitinib. Toxicity was 'acceptable', the DMC said.

The trial included 154 patients who were given best supportive care and either placebo or sunitinib 37.5 mg/day continuous daily dosing. The interim analysis found that median progression-free survival was 11.1 months with sunitinib versus 5.5 months for placebo.

Dr Raymond said the key remaining question is whether sunitinib significantly improves overall survival in this patient group. 'There are few medical options for advanced pancreatic islet cell tumours so our trial is important because it opens up the possibility for future treatment.'

The most common adverse events reported in the trial with sunitinib treatment were diarrhoea, nausea, vomiting, asthenia and fatigue.

Rhonda Siddall

(*who was sponsored by Pfizer to attend the meeting*)

(*EJC Supplements 2009 7:2 #6501*)

...and in GIST

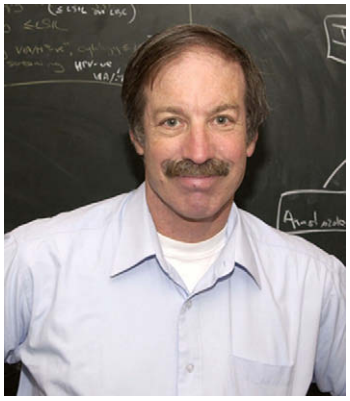
The UK's National Institute for Health and Clinical Excellence (NICE) has recommended sunitinib (Sutent) for the second-line treatment of advanced gastrointestinal stromal tumours (GIST).

The announcement, on September 24, 2009, was based on the benefits seen in time to tumour progression and progression free survival over best supportive care alone. The Appraisal Committee said the benefits were such that a 'substantial' improvement in overall survival with sunitinib treatment 'was probable'.

NICE's decision was based on a Phase III trial showing sunitinib increased time to tumour progression 27.3 weeks versus 6.4 weeks with placebo ($p<0.0001$). Following these findings, 84 % patients receiving placebo switched to sunitinib. Updated analyses demonstrated a median overall survival of 73.9 weeks in the sunitinib arm versus 64.9 weeks in the placebo arm ($p = 0.161$).

PODIUM

HPV testing 'needed now'



Professor Jack Cuzick (Wolfson Institute of Preventive Medicine, Cancer Research UK Centre for Epidemiology, Mathematics and Statistics, London, UK) spoke at the ECCO 15–34th ESMO Congress on the need to replace the Pap smear with screening for the human papilloma virus (HPV).

What is the current situation?

HPV vaccination is being introduced in different ways in different countries. The UK, for example, is very organised through its school-based programme and indications are that coverage is over 80 percent, which is crucial. HPV is the primary cause of cervical cancer and not only can we vaccinate against two of the types but screening for HPV is also better than cytology. It has been shown to be a much more sensitive test in over a dozen studies and it gives a longer period of protection. HPV screening could be done once every 5 years, or even less often, starting at age 25 or 30.

We should seize the opportunity to move from cytology to HPV screening, recognising that in about 10 years' time, girls who are being vaccinated now are going to need a more sensitive test. By then, HPV testing will undoubtedly have become more specific and it makes sense to use a simple automated laboratory test rather than to have batteries of cyto-screeners looking at slides.

What have the studies on HPV testing shown?

The many studies throughout Europe have all shown that HPV testing picks up about 50% more abnormalities than cytology. There's emerging evidence that the duration of protection after a negative HPV test is at least 6 years, whereas for cytology it starts to wane after 3 years. It makes a lot more sense to do a good test infrequently than a less effective test regularly.

Should HPV testing replace the Pap smear now?

It should have been done last year! There should be a transitional phase in which both tests are used. In our, and many others' experience, if you do both, you find that cytology is very rarely positive for significant disease unless HPV is also positive. Therefore, the next step is to use HPV testing as the primary screen and use cytology only in those who are HPV positive to see whether they need immediate referral or a repeat test in a year's time. HPV testing has been delayed longer than I expected and there is a need to move forward now.

Why the delay?

Partly because we have cytology which, let's be clear, has been effective in reducing the incidence of cancer by the order of 50%, may be even 70%, in the best circumstances. However, in many places it has been ineffective. Unfortunately, governments tend to consult cytologists, who have a vested interest in keeping the status quo. This has slowed down the implementation of better approaches.

Is there a cost difference between HPV and cytology tests?

The HPV test is more expensive although the actual cost for large volumes may yet come down. Also, if you can do it less frequently, then even at a reasonably high cost, it will save health services money.

What HPV tests have been approved to date?

There's one FDA-approved test which is commercially available. There are several others which are almost fully evaluated and are due up for FDA approval fairly soon. In Europe, there are several CE marked tests.

What studies are you involved in?

We're continuing to evaluate new tests in referral populations. I have also been working for many years on a stepwise approach to the introduction of HPV testing. Now that we've moved to liquid cytology in the UK, I'd like to set up a pragmatic study in which women would be informed that their sample is either to be tested by cytology or by the HPV test, and give them the chance to opt out. It would include a million women aged over 33 years, who would be randomised so that 3 would have cytology and one would have HPV testing. It would lead to a small reduction in the workload for cytology while providing a phased introduction for HPV testing. There are 3 to 4 million smears a year in the UK so it wouldn't take long.

We're keen on this phased transition as part of a demonstration project in which we continue to learn. We know that it will detect more cervical intraepithelial neoplasia and that the duration of safety will be longer but the last issue is whether or not it reduces cancer rates. A phased introduction will give us the scientific information which will be valuable in the long term.

What are the next steps in HPV testing implementation?

The American approach has been to go for a halfway house and approve joint testing. In Europe, there's no routine use of HPV testing, everything is still research-based. It's frustrating as all of the early studies on HPV testing as a primary screening test were done in Europe yet the powers that be have dragged their feet in implementation. However, the tide is turning and there is more acceptance that this is the way to go. But it's impossible to say whether it will be next week or in another 5 years.

Robert Day-Webb