

Think BIG News - June 2015

The monthly newsletter of the largest global network of academic groups dedicated to breast cancer research



We will find a cure for breast cancer through global research and collaboration.

Putting patients first

Patients are first and foremost the reason why we do breast cancer research. The questions we try to answer, the treatments we try to improve, the cures we are trying to discover — they are all driven by **the needs of patients and their families**.



In this issue of Think BIG News, we **meet Susan Knox, Executive Director of Europa Donna, the European patient advocacy organisation**. Susan talks about the needs of breast cancer patients and why research is important to them.

Also included in this issue are the highlights from the **American Society of Clinical Oncology (ASCO) Annual Meeting 2015**. We are proud to announce that BIG Associate Scientific Director Dr. Dimitrios Zardavas, received an ASCO Merit Award at this year's conference for his work examining the prognostic relevance of the PIK3CA mutation in early-stage breast cancer. We present an interview with Dr. Zardavas about his work.

Finally, mark your calendars for some upcoming BIG events: the **BIG Garden Party and the BIG-athlon!**

Meet Susan Knox

Executive Director, EUROPA DONNA



EUROPA DONNA, the European Breast Cancer Coalition, is a non-profit breast cancer organisation, gathering members throughout Europe. This organisation **plays a key role in advocating on behalf of European patients.**

What is Europa Donna?

The European Breast Cancer Coalition, (ED) is an independent non-profit organisation whose members are affiliated groups from countries throughout Europe. **The Coalition works to raise awareness of breast cancer and to mobilise the support of European women** in pressing for improved breast cancer education, appropriate screening, optimal treatment and care and increased funding for research. EUROPA DONNA represents the interests of European women regarding breast cancer to local and national authorities as well as to institutions of the European Union.

What are the most important benefits of an organisation like ED for patients?

First of all we are advocating on behalf of patients to ensure that all women in Europe have access to accurate and up-to-date information about breast cancer. **Our role is also to ensure that they all have equal access to state of the art services** for early detection, diagnosis, treatment and follow-up for this disease.

This means that the women affected by breast cancer can rely on the information and education provided by our organisation. The strength of Europa Donna really lies in uniting women of many different countries and cultures to achieve common goals based on scientific evidence.

Through our information, education and policy/public affairs activities, patients now have access to up-to-date accurate information and are in a position to take informed decisions about their care and treatment.

What do you think is important about breast cancer research, from a patient's perspective?

Moving research forward is essential to breast cancer advocacy and to patients. **The hope for patients in the future rests in the hands of researchers and research groups to**

develop new and better treatments for the many types of breast cancers that exist. The advances of the last 30 years are evidence of this –starting with the development of endocrine therapy.

Research represents the hope, the future, and the real possibility of eradicating this disease once and for all. Given the significant increase in incidence across the world highlighted in the recent report from the IARC, we need research of all types to understand how the disease develops, why it is increasing and how to stop it.

Europa Donna considers our collaboration on research projects to be one of our most important strategic pillars for the next 5-10 years.

How do you see advocacy evolving? What are the priorities of ED for the next years? What are the upcoming challenges?

Advocacy must evolve as needs and issues change. Some priorities remain the same, such as – among others – establishing specialist breast units in all countries according to the EU Guidelines for quality assurance in breast cancer screening and diagnosis, developing national breast cancer registries, and furthering breast cancer research.

In addition, we have identified new priorities. Among them, breast cancer prevention was identified as a key concern and led to the launch of our Breast Health Day campaign in 2008. Now all of our ED countries agree that this is a priority for ED moving forward. The Breast Health Day is held annually on 15 October and provides women and girls with information about lifestyle changes that can help prevent a diagnosis of breast cancer in the future. The latest priority added is survivorship. This is a new area; **women now live longer after being treated for breast cancer but they have multiple needs and concerns that still need to be addressed**, possibly for many years, such as fatigue, psycho social support, help with work related issues, etc.

Why is it important for ED to collaborate with associations such as BIG?

Our collaboration with BIG is essential because it provides a way for us to understand the current research that is being undertaken, to provide input on clinical trial protocols and materials that may be helpful to patients and in trials. We hope in this way to contribute to helping ensure that trials are run more smoothly, recruit more easily and with better patient understanding and, as a result, with more success and speed in bringing new treatments to patients. Furthermore, this collaboration enables us to educate our advocates in all of our countries so that they may develop research collaborations at the national level, increasing exponentially our ability to provide patient input into breast cancer research. **We are represented in BIG's Scientific Meeting and serve on the Steering Committees of the MINDACT trial, the OLYMPIA trial and the new AURORA research programme on metastatic breast cancer.**

Our aim is to make our contribution to ensuring that state of the art research is conducted. Research that will ultimately provide the much needed cures for this disease.

Do you collaborate with other patient advocacy organisations in the world?

We provide information and guidance to breast cancer groups that are setting up especially in South America, in the Middle East, and in Africa. **The realities in each country are different, but there are also many common aspects between them.** Many members of ED come from countries that are still at the beginning of the advocacy journey. We frequently send ED Board members directly to countries to help them better understand the advocacy work. We also invite advocates from other countries to attend our Pan-European Conferences. In the area of prevention, each year we offer all our materials for the Breast Health Day to all groups interested, everywhere in the world. This is an area we can all agree on, and information programs are not expensive

to implement. We also have ongoing collaborations with other cancer patient organisations across Europe. In this way we are able to network and share significant ideas and methods that can help to improve the effectiveness of our organisations.

2014 marked the 20th anniversary of ED. What has changed in two decades of patient advocacy work?

In the early 90's there was no European breast cancer advocacy movement or organisation, so a great deal has changed since the formation of ED in 1994! **We started with groups in 12 countries and now have member groups in 47 countries.** Right after its creation, the ED Board agreed on 10 main goals and made a commitment that all messages and activities that would be undertaken by the coalition to achieve these goals needed to be evidence-based. Immediately we began collaborating with experts and specialist groups like EUSOMA¹, EORTC², IARC³, and later BIG, to develop information, education, and policy programmes that would advocate for the provision of state of the art breast services needed by women across Europe. **We have made a lot of progress in 20 years, particularly in the implementation of population-based mammography screening programmes and specialist breast units.** You can see a summary of our advocacy work in our 20 year brochure on our website www.europadonna.org.

Highlights from ASCO

June 2015

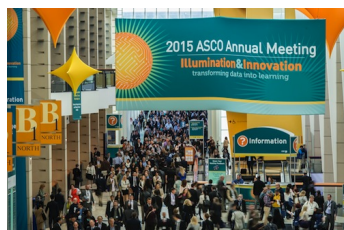


Photo © ASCO/David Eulitt 2015

The American Society of Clinical Oncology (ASCO) Annual Meeting 2015 took place recently in Chicago, USA. With approximately **30,000 oncologists and other scientists** involved in the care of patients with cancer and/or cancer research, the meeting provided the results of **important clinical trials with impact on the field of breast cancer oncology**, including:

- The **ExteNET study**, examining the effects of treating women with HER-2 positive breast cancer with a molecular inhibitor
- The **MARIANNE trial**, studying a new drug combination also targeting patients with HER-2 positive breast cancer
- The **NRG Oncology / NSABP B-35 study**, focused on the endocrine treatment of patients with Ductal Carcinoma In Situ (DCIS). Findings indicate a certain pattern of increased efficacy of anastrozole over tamoxifen among younger women with DCIS.
- **The PALOMA3 study**, addressing the issue of endocrine resistance in the metastatic setting of luminal breast cancer.

For a summary of the scientific results of these trials, visit our website.

Interview with Dr. Dimitrios Zardavas, Associate Scientific Director at BIG

Awarded the ASCO Merit Award, for his analysis of *PIK3CA* mutations' prognostic relevance in early breast cancer



Congratulations for presenting the results of this analysis at the recent ASCO annual meeting, and could you please describe the award you received for this work?

I received the ASCO Merit Award. It is an award given by the American Society of Clinical Oncology (ASCO) to **young cancer investigators**, based on the **scientific merit of their work presented at the annual meeting**.

Could you tell us a little bit about the work you did for which you were recognized with

this award?

In breast cancer there is **genomic aberration called *PIK3CA* mutation, which is one of the most common aberrations seen in early-stage breast cancer**. During the last 10 years, many different investigators around the world have wanted to know if this common aberration was useful in determining breast cancer prognosis.

Over 20 studies have been conducted around the world, trying to determine the impact of this aberration on the progression of early-stage breast cancer. However, the studies were focused on different sub-sets of patients, including age, disease characteristics, etc. Of note, **these studies reported inconsistent results** concerning the prognostic relevance of *PIK3CA* mutations. Some identified this mutation as a positive prognosticator (meaning it led to better patient outcomes); others found it to be a negative prognosticator; still others found it was not significant.

As a result, **we did not know the prognosis for the patients with this common mutation**. That fueled our motivation, together with Dr. Sherene Loi from the Peter MacCallum Cancer Center, Melbourne, Australia, to conduct **a pooled analysis of all the studies that assessed the potential prognostic relevance of this mutation**. We wrote a protocol about the research questions we would like to address, then reached out to all the investigators who conducted these studies and asked if they would provide their patient data. Most of them accepted, but this process took over a year.

The investigators sent us their data sets with individual patient data. **We pooled the data together for more than 4.500 patients** with early stage breast cancer, including information about the mutational status of the *PIK3CA* gene, characteristics of the disease, the treatments received and the clinical outcome. We were able to achieve a much higher statistical power by pooling the data.

We found some **interesting results**, with some of them not seen before: *PIK3CA* mutations were overall associated with positive prognostication (better patient outcomes) – seen mostly during the first 3 years after the primary diagnosis; after that the positive impact fades. This indicates that **the mutation could potentially protect patients from early relapses**.

Additionally, this positive prognostication derives from the subset of **young women (age 50 and below)**. For young women below 50 with hormone-sensitive disease, this finding could have important clinical consequences, because it **could spare them chemotherapy**; they could simply be treated with a PI3K blocking agent and endocrine treatment.

What we did not assess was what the predictive value of these mutations is, meaning whether they would help us identify which patients would respond best to treatment. BIG is currently conducting some clinical trials trying to assess if *PIK3CA* mutations have predictive value for identifying patients whose breast cancer disease will be sensitive to PI3K blocking agents. There are 2 trials currently ongoing under the BIG umbrella, both conducted in the neo-adjuvant (i.e. pre-surgical) setting: NeoPHOEBE, the results of which will be presented at the San Antonio Breast Cancer Symposium in December 2015, and the ongoing LORELEI trial, which focuses on older women with early stage ER+ breast cancer. This study looks at providing endocrine treatment in the neo-adjuvant setting with or without an agent that targets this mutation.

How will this recognition help bring attention and/or help you make more progress in this area of research?

The publication of this work in the form of a full report, after review by the collaborators, will bring attention to the results of our study, and should attract the attention of other breast cancer research groups, many of whom already do research on this mutation.

Do you have any final remarks on how you felt about receiving the award?

I would like to thank the Co-Principal Investigator of this project, Dr. Sherene Loi. I would also like to thank the numerous investigators who agreed to collaborate for this study.

I am very happy about the work itself, and the results. I feel very honored to have the trust of the investigators who accepted to collaborate and provide their data sets for this study.

REGISTER NOW! 10/10/15



On Saturday October 10, BIG against breast cancer will organise the **very first BIG-athlon** in the beautiful surroundings of the tri-border area in Ouren (Belgium). During this sports and family event, individuals and company teams can **run, bike or walk** to actively support metastatic breast cancer research.

To register, visit www.big-athlon.org

SAVE THE DATE - 04/10/15 BIG Garden Party



Help us kick off the "BIG Time for Baby" fundraising campaign at the BIG Garden Party, which will take place at the Château de Grand-Bigard on 4 October 2015!

This **unique location**, a castle of the XVII century, is part of the Belgian Patrimony and opens its doors to the public only once a year, during the flower show. The BIG Garden Party is an exceptional opportunity to spend a relaxing day at this beautiful place.

At this special event, parents can relax while their children are entertained with many fun activities. We will use this occasion to launch the crowdfunding campaign for a project to **help young women being treated for breast cancer**, who want to start their families, **to safely become pregnant**.

For more information, contact elodie.treillard@bigagainstbc.org



To learn more about BIG against breast cancer, please visit our site:

www.BIGagainstbreastcancer.org



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