

## Paolo Paoletti, MD, Senior Vice President, Oncology Medicine Development Center, GlaxoSmithKline, Philadelphia, PA



Dr. Paolo Paoletti, MD

Dr. Paolo Paoletti joined GSK in 2004 and is responsible for the late-stage development of the oncology compounds in the GSK pipeline and post marketing studies.

Dr. Paoletti holds a medical degree from the University of Pisa, Italy, and went on to complete post-graduate studies in Pulmonary Diseases and Nuclear Medicine. Dr. Paoletti served as Professor of Pulmonary Medicine at the Division of Internal Medicine, University of Pisa, and was also the recipient of a National Institutes of Health (NIH) Fogarty Fellowship at the University of Arizona, Division of Respiratory Sciences. From 1995 to 2004 he worked at Eli Lilly, first as Medical Director in Italy and then in the US where he played a critical role in the development of Gemzar® (gemcitabine) and Alimta® (pemetrexed).

At ASCO this year GSK announced the creation of the Gianni Bonadonna Breast Cancer Award and Fellowship in honor of the outstanding contributions Dr. Bonadonna made to the field of breast cancer research. This is a multi-year grant in excess of one million dollars which will support ASCO and the ASCO Foundation. The award will acknowledge clinical and translational researchers of merit in the field of breast cancer research and enable emerging investigators to undertake new patient-oriented research under the mentorship of the awardees. At the recent ASCO Breast Cancer Symposium in San Francisco the first awardee of the Gianni Bonadonna Breast Cancer Award was announced – Dr. Daniel Hayes, Clinical Director of the Breast Oncology Program at the University of Michigan Comprehensive Cancer Center. We spoke with Dr. Paoletti about the award and the oncology franchise at GSK.

**OBR:** Please explain the genesis of the idea to establish an award in honor of Dr. Bonadonna. How long has it been in the works? What was Dr. Bonadonna's reaction when he heard the news?

**PP:** I was at a cancer meeting in Italy in December of 2006 and Dr. Bonadonna was there to receive an award for his contribution to clinical research in cancer. During a coffee break I heard that some fellows (young doctors) did not know about Dr. Bonadonna's research and his groundbreaking work. The same evening I had the honor to sit close to Dr. Bonadonna during the dinner and I was able to appreciate his passion about science, his connection to patients, and how it was difficult for him to live as a patient with a disabling disease. Flying back to US I thought "We need to recognize the extraordinary accomplishments of this man!" Dr. Bonadonna made huge contributions to oncology research in spite of his career being cut short for health

reasons, and it was clear to me that we needed something in place to be sure his legacy is felt for generations. As soon as I got back to America I called Dr. Hortobagyi [ASCO Immediate Past President] to ask if ASCO would consider something like this, and he immediately said, "Let's do it." Within 3 months we had approval from GSK and the management of ASCO. We were able to announce the award at ASCO '07 in Chicago just 6 months later.

Dr. Hortobagyi and I called Dr. Bonadonna to tell him about the award and we could immediately hear the fantastic enthusiasm and excitement. He called it a "beautiful surprise." He has since sent us letters and thank you notes to show his appreciation.

**OBR:** Please tell us more about the award. Will this be an annual award? Ongoing indefinitely? Tell us about the selection process. There is also the support of the research fellow



*we'd like to hear about. What kind of financial commitment has GSK signed up for with this award?*

**PP:** This is an annual award that will be ongoing forever as far as I'm concerned. GSK has pledged \$1.3 million over 5 years, and this grant will go in an endowment to ensure the Award, Lecture and Fellowship last indefinitely.

ASCO does all the selection without any input from GSK, and there are two components to the award. The first awardee is Dr. Daniel Hayes and because of his efforts he received a \$10,000 award and gave a Lecture at the Breast Cancer Symposium. At a later date Dr. Hayes and ASCO will reveal the recipient of a \$50,000 Fellowship Grant who will be an early-career breast cancer researcher at the University of Michigan.

**OBR:** *Why does GSK want to support external research? Do you think recognition of research in academia correlates well with the innovation you are trying to establish at GSK?*

**PP:** Research, especially cancer research, cannot be done solely within the company. To move the field forward as efficiently as possible there has to be collaboration between industry and researchers, and this award will hopefully encourage that collaboration.

At GSK we wanted to do something different. We want to make a statement that we are excited to provide innovative contributions to the field of cancer research, and to be a part of the future of cancer research, because we are an innovative company with a strong future. I must tell you that my management was very excited to be part of this important initiative.

**OBR:** *Speaking of GSK, Tykerb® (lapatinib) made a splash this year with approval and launch. Please give us an update on how Tykerb® (lapatinib) is performing in the US to date, and the future clinical development plans for Tykerb® (lapatinib).*

**PP:** Tykerb® (lapatinib) represents a turning point for GSK. By bringing Tykerb® (lapatinib) to market we have been promoted to the major leagues of oncology, and now we are starting to compete with the major players in oncology and the beginning is very promising.

We're very excited about the future for Tykerb® (lapatinib), and as such we are investing in further clinical development in breast cancer. We're also developing Tykerb® (lapatinib) in head and neck, gastric cancer and renal cancer.

**OBR:** *Let's not forget about Hycamtin® (topotecan HCI) and Bexxar® (Tositumomab and Iodine I 131 Tositumomab). How are they performing in their respective markets?*

**PP:** Hycamtin (topotecan HCI) is experiencing fast growth in the 2nd line Small Cell Lung Cancer (SCLC) setting which we're excited about. We've also submitted the NDA for Oral Hycamtin® (topotecan HCI) in the US and in Europe.

Bexxar® (Tositumomab and Iodine I 131 Tositumomab) is an incredible drug. We hope to see the results of the SWOG study comparing CHOP chemotherapy + Bexxar® (Tositumomab and Iodine I 131 Tositumomab) vs. CHOP + rituximab as soon as the end of 2008. If we see a demonstration of strong efficacy we expect this to help overcome the intrinsic difficulties of delivering radiopharmaceuticals. Bexxar® (Tositumomab and Iodine I 131 Tositumomab) can help patients with just one dose, and if the efficacy is positive I'm sure doctors will do what is best for patients.

We also received US approval for Arranon® (nelarabine) in October of '05 for pediatric T-cell acute lymphoblastic leukemia (T-ALL) patients and recently in Europe with the name of Atriance. Arranon®/Atriance (nelarabine) took us 10 years to get approved but is providing a magnitude of difference for T-ALL patients. This is a very small patient population and really is another demonstration of the commitment at GSK to patients with cancer and their families.

**OBR:** *With Tykerb® (lapatinib) and a positive buzz about the pipeline, GSK Oncology seems to have made great strides in establishing itself as a leader in the oncology field. Please tell us what has happened lately.*

**PP:** The last three years at GSK have been nothing short of a revolution. In the last three years we [cont. on pg 46](#) >>

have moved 5 drugs into Phase 3 and launched a groundbreaking innovative product. We have also tripled the number of people working at GSK Oncology, including some exciting leaders in the field such as Barbara Weber (world expert in breast cancer) and Thierry Le Chevalier (world expert in lung cancer) which shows that GSK can attract high caliber individuals to its programs.

Over a 10 year period Genentech successfully launched 4 excellent new products in oncology, and over the next 10 years we expect to launch 6-8 new oncology products.

I look at Genentech as an extraordinary success story in oncology, and yet I think we can accomplish as much success or more than they have. I don't think it is too bold to say that GSK has the richest late stage pipeline in oncology.

**OBR:** *What products in the GSK hematology and oncology pipeline are you most excited about today? We're also interested in hearing about products you are developing with partners.*

**PP:** Pazopanib is a very exciting multi-targeted compound, inhibiting VEGFR -1, -2, -3, PDGFR, and c-kit. At ASCO we presented Phase 2 progress in renal cell and ovarian cancer, and soft tissue sarcoma with encouraging enough results to take us into Phase 3.

MAGE-A3 trials are ongoing in non-small cell lung cancer (NSCLC). The MAGE-A3 antigen-specific cancer immunotherapeutic (ASCI) is an innovative approach to treatment and may be the first treatment of this type to be successful. The MAGE-A3 ASCI is in phase III and it will be tested in early stage lung cancer (after surgery) and only in patients who overexpress the antigen MAGE A3. This will be the largest phase 3 study in adjuvant NSCLC. And of course there are the other compounds we are developing with Exelixis which we are excited about.

We are also excited about ofatumumab, a next generation fully human monoclonal antibody in late stage development for CD20 positive B-cell chronic lymphocytic leukemia (B-CLL) and follicular non-Hodgkin's lymphoma (NHL). And we continue to be very pleased with the development of Promacta® (eltrombopag), or called Revolade®

in Europe. This important oral agent is an investigational non-peptide platelet growth factor, currently in Phase III for chronic idiopathic thrombocytopenia purpura (ITP), and being studied in other forms of thrombocytopenia.

**OBR:** *What accomplishments are you most proud of in your three year tenure at GSK, and what are your hopes and plans for the future of GSK Oncology?*

**PP:** I feel as though I couldn't be at a better place at this time in my career. I am most proud of having delivered two new products to patients since I began at GSK but that's not all of it. We have built, and continue to build, a fantastic infrastructure supported by our vision.

As you can imagine, we have a lot to do to deliver on this pipeline. My hope is to realize the potential of this wonderful pipeline and my dream is to move away from the traditional development approach, deliver targeted drugs to the right patients, and thus transform the oncology development process. Hence, reduce as much as possible the use of chemotherapy, transforming cancer in a chronic disease and, hopefully, by using the new generation of drugs as early as possible to cure the disease.

**OBR:** *Congratulations on setting up and implementing the first Gianni Bonadonna Breast Cancer Award and we look forward to tracking the future events and accomplishments at GSK Oncology.*



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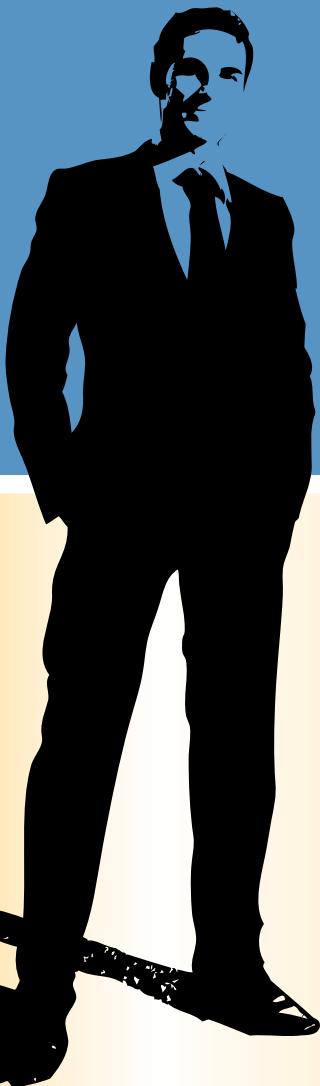
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