



Craig W. Philips, Vice President & General Manager, Bayer Healthcare



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Craig joined Berlex Laboratories in January '04 as Vice President, Oncology Marketing and was promoted to Vice President and General Manager of the Oncology Business Unit in October of 2004. With the merger of Bayer Healthcare and Schering AG Craig has emerged as Vice President and General Manager of the Oncology Business Unit at Bayer Healthcare.

Prior to joining Berlex, Craig has held various positions of responsibility, including international roles, at Schering-Plough and Bristol-Myers Squibb. Craig has more than 20 years of experience within the oncology industry.

On September 20th Bayer and Genzyme announced the FDA had approved a supplemental biologics application for Campath® (alemtuzumab) and granted regular approval for single-agent Campath for the treatment of B-cell chronic lymphocytic leukemia (B-CLL).

Campath was initially approved in 2001 under accelerated approval regulations and the FDA has determined that this study, presented at ASH '06, fulfilled their post marketing commitment. The new indication for Campath is as a single-agent therapy for B-CLL patients. Campath is the only monoclonal antibody approved for B-CLL.

Bayer Oncology has had a busy year. The merger with Schering AG boosted the portfolio of marketed oncology products to three: Nexavar, Campath, and Leukine. Like any integration of two companies there are a host of concerns at every level, but with a flagship product like Nexavar leading the way Bayer Oncology has an opportunity to leverage their products and pipeline to become a leading oncology company.

We spoke to Craig Philips, VP of the Oncology Business Unit at Bayer, to better understand the Campath opportunity, the performance of Nexavar, and find out more about the merger.

OBR: *Let's talk about Campath first. The new indication positions it further forward in the treatment algorithm. Were physicians already using Campath in the first line setting since the presentation at ASH '06, and do you expect to see a significant spike in market share since the FDA gave you approval in that setting?*

CP: There are about 15,000 newly diagnosed CLL patients in the US each year, and the refractory setting that we were previously operating in is only about one-third of that size. Campath has established itself as the cornerstone of therapy in refractory CLL, and the significance of the new indication is that it brings single-agent Campath use to many more CLL patients.

We filed the sBLA in early '07 shortly after the presentation of the data at ASH '06. We have seen expanded use of Campath across all lines of therapy, including first line and third line, but also in combination with other agents since the presentation of that data. There is an increasing body of data coming out suggesting the role of Campath may fit in different lines of therapy and in combination with other agents. We think there is still a lot of growth left in the market, especially in the first line setting.

The efficacy data with Campath is very well established, but also the safety profile appears to be comparable to chlorambucil, which is considered a relatively innocuous agent to treat CLL. Therefore we expect to see a strong level of interest and enthusiasm because [cont. on pg 48 >>](#)

of the strong efficacy data, a new indication from the FDA, and a comparable safety profile.

OBR: *Given the success with Campath as a single agent in CLL, do you plan to study it in combination with other agents, and in other hematologic malignancies?*

CP: We have a long-term development plan consistent with that of other oncology drugs. Right now we're focusing on three areas of study: high-risk CLL patients, combinations with cytostatics and monoclonals, and in consolidation therapy. We also announced recently that we have begun a Phase 3 study of Campath in multiple sclerosis after seeing a significant reduction in the risk of relapse in a smaller Phase 2 study.

OBR: *We'd like to turn to Nexavar now. Nexavar has been on a roller coaster with the Sutent data and performance dominating the renal cell carcinoma market. But arguably the biggest story at ASCO '07 was the hepatocellular carcinoma (HCC) data with Nexavar. You must have been excited that the Nexavar data in HCC was selected for the plenary session. What reaction have you had from US oncologists regarding the HCC data presented at ASCO and ECCO this year?*

CP: Both presentations—ASCO and at ECCO—were huge home runs because of the high unmet need and limited therapeutic options for this tumor type. We now have two studies in HCC—the US/European study called SHARP and the Asian HCC study—that have been halted because of the high clinical activity of Nexavar. At ASCO we presented the first look at the SHARP data and at ECCO we presented data from both studies.

The presentations have been very well received and we are seeing a high level of interest among oncologists and among patients. There have been few options available in this setting.

OBR: *If you are seeing uptake in HCC now, what about reimbursement for Nexavar in the HCC setting?*

CP: Believe it or not, the market is telling us that because of the lack of therapeutic choices in HCC the reimbursement has not been troublesome overall. Nexavar is the

first drug to demonstrate a significant overall survival advantage in HCC, and payers are aware of the high unmet need and payers have been willing to reimburse products in these under served medical segments.

OBR: *And the sNDA filing for Nexavar in HCC is complete and you expect to hear from the FDA regarding approval before the end of the year?*

CP: The sNDA for Nexavar in HCC was submitted in June of '07, right after ASCO, and the FDA granted us an accelerated review, meaning that we expect to hear one way or the other regarding the application by the end of this year.

OBR: *What other development hopes do you have for Nexavar in the next couple of years?*

CP: We are continuing to study Nexavar in renal cell cancer in combination with other agents. We are also anticipating a broad HCC program although we're waiting for FDA approval before we announce further development plans for Nexavar in HCC. We had a setback in melanoma but we are still studying Nexavar in Phase 3 for melanoma with a new study design, we have a Phase 3 underway in NSCLC comparing standard doublet therapy +/- Nexavar, and finally our breast program is in Phase 2. As you can see Bayer and Onyx have a strong commitment to Nexavar and we continue to fund studies in several disease settings.

OBR: *And on to the merger with Schering AG. What is your identity now? What has gone right? What has been frustrating you? How has the merger changed the dynamics within the commercial teams?*

CP: On January 1 '07 we began operating as the oncology group within Bayer Healthcare. I would characterize this merger as different compared to others. Schering AG (Berlex) brought Campath and Leukine and already had a strong oncology emphasis and priority, and therefore the integration of Bayer and Schering has been going well.

There hasn't been a need to tackle internal cultural differences because both companies brought a strong and close to equal oncology footprint. This merger wasn't about combining and reducing head count. Instead, the oncol-



ogy group at Bayer today is larger than either company was separately.

Mostly I've been frustrated because we are still spread among three locations. It is estimated that we'll all be in one location (Wayne, NJ) by January, and at that time I think we'll be able to come together as a team and even further develop our own culture.

OBR: *You suddenly find your commercial team has responsibility for three products. Does Nexavar demand the majority of attention from the commercial teams at Bayer Schering Oncology? Is Campath a priority now that you've got the new indication? Are you spending any time on Leukine, or has it decreased in priority because of the needs of the other two products?*

CP: To answer that question I'll use the sales force as an example. We now have two equally weighted sales forces: one for hematology and one for oncology. While the two groups are focused on their respective products, there is good synergy between them. We find that at the customer level there seems to be more satisfaction with our sales forces working together to bring better service to the customer.

Leukine remains important to us. Leukine is our product, and because we have our own identity with that product we are careful to spend time on it.

OBR: *Tell us about the oncology pipeline at Bayer, and what is most exciting at this time?*

CP: One of the great things that came out of this merger is the pipeline. We have products in development such as a bisphosphonate for bone metastases in breast cancer in Phase 3, an epothilone (microtubulin stabilizer) in Phase 2 for several different indications, we have immunocytokines that are going into Phase 2 this year, and we have an anti-angiogenic product which is in Phase 2, in addition to proposed label expansions for existing products we have discussed already.

OBR: *What are the two things you most want to accomplish in the next six months at Bayer Schering Oncology? The next year?*

CP: In the near term I want to maximize the role of Campath in first-line CLL, and, following FDA approval, have a successful roll-out of Nexavar into the HCC market where there is a tremendous unmet need. I want to advance the clinical programs that are currently under way. In the long term I mostly want to build on the foundation that already exists here at Bayer, and become a top five oncology company in the next five years. We can accomplish this because in the next four months we'll have two new indications, and in the next five years we expect to have two new products and three to five new indications.

OBR: *You've got a full plate merging the companies and developing and promoting two exciting targeted therapies. We wish you well in establishing Bayer Oncology as a premier oncology company.*



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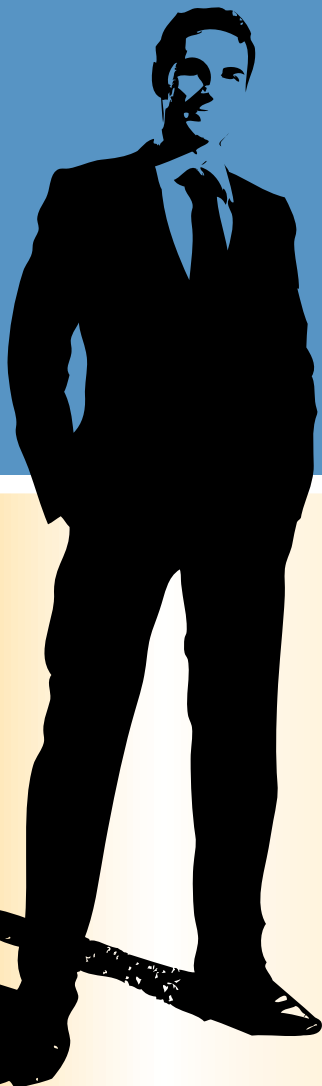
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