

## On-conversation with Richard Gaynor, MD, Vice President of Cancer Research and Global Oncology Platform Leader, Eli Lilly and Company



Richard Gaynor, MD

With its acquisition of ImClone in 2008, Eli Lilly and Company currently has an unprecedented number of molecules in clinical development. This strategic purchase creates one of the most innovative oncology franchises in the biopharmaceutical industry and offers targeted therapeutics and oncology agents alongside a pipeline that spans all phases of clinical development.

The company's combined oncology portfolio now reaches a broader array of solid tumor types that includes lung, breast, ovarian, colorectal, head and neck, and pancreatic cancers. One of Lilly's most promising areas of research and development concerns personalized medicine, or tailored therapies. Their tailoring strategy, ultimately, is to provide the right medicine, at the right time, at the right dose, for the right patients. Recently, we interviewed Dr. Richard Gaynor, vice president of Eli Lilly's cancer research and global oncology platform leader. Dr. Gaynor informed us on how the company's strategy is evolving.

**OBR:** We know personalization of cancer therapeutics is a goal for all stakeholders, but how successful has Lilly Oncology been at developing tailored products?

**RG:** The tailoring strategies we are using for our commercial products, such as Alimta and Erbitux, and the molecules we have in development are very important to our researchers, physicians, payers, and patients. Our goal is to maximize benefit and decrease side effects or ineffective treatment.

For example, if you look at the indications for Alimta and Erbitux, they are tailored to specific patient populations. With Alimta, it is targeted for nonsquamous, non-small-cell lung cancer (NSCLC) patients. It is not indicated for patients who have a different type of NSCLC called squamous cell carcinoma. With Erbitux, the labeling change has been FDA approved to include infor-

mation saying that Erbitux is not recommended for the treatment of colorectal cancer in patients who have K-ras mutations in codon 12 or 13. As we now know, an estimated 40 percent of patients with colorectal cancer have K-ras mutations, while the other 60 percent have a wild-type K-ras gene.

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With these two drugs you can see how tailoring has been a very important strategy. We are embracing this strategy for the rest of our pipeline, as we see it as an important component to our long-term strategy.

**OBR:** Speaking of Alimta and Erbitux, can you give us an update on the R&D of the products?

**RG:** We have four important Phase 3 trials ongoing with Alimta. The first is in combination with the targeted agent, Avastin, in metastatic lung cancer. The goal of the second trial is to determine the efficacy of Alimta in patients who receive this as initial treatment of lung cancer and then move on to maintenance therapy. The third study is to test Alimta in combination with radiation therapy in locally-advanced lung cancer as part of a curative regimen—which includes about 10%-15% of the lung cancer population. Finally, we're studying Alimta and platinum therapy in head and neck cancer. We should have results for this trial sometime next year.

With Erbitux, we have a number of ongoing studies in a variety of differ-

ent cancers in addition to head and neck and colorectal cancer, including gastric and esophageal.

**OBR:** *With the purchase of ImClone, you've acquired quite a significant number of molecules for development. What are some of the more innovative ones you are developing?*

**RG:** Over the past three or four years, both Lilly and ImClone have focused on oncology, and a number of these molecules are either moving into or are already in Phase 1 and Phase 2 development. At the current time, the combined companies have 23 molecules in clinical testing—a pretty significant number—and most of these have biomarker approaches.

In terms of promising late-stage ImClone pipeline molecules in Phase 3 or soon-to-be Phase 3, we have a number that we feel are bolstering our pipeline. For instance, 1121B is a fully-human monoclonal antibody that targets the VEGF receptor being tested with chemotherapy in metastatic breast cancer patients.

Another molecule that will be going into Phase 3 is 11F8. This is an antibody that targets the epidermal growth factor receptor, much as Erbitux targets it, but it's a fully-human antibody. It targets a similar epitope on the epidermal growth factor receptor as Erbitux.

A third ImClone molecule—A12—may also be going into Phase 3 soon. It is a fully-human monoclonal antibody that targets the insulin-like growth factor-1 receptor (IGF-1R).

A12 has the potential to work with a variety of other targeted agents, so it's a very attractive molecule for us.

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**OBR:** *What's the latest on enzastaurin in the lymphoma trial?*

**RG:** Enzastaurin is an oral kinase inhibitor that is in a Phase 3 trial in the maintenance setting for patients with diffuse large B-cell lymphoma; for patients treated with chemotherapy/Rituxan, and if they go into remission, they're put on enzastaurin to see if it can help prevent relapse. We are investigating enzastaurin in lymphomas because data has shown it may help to slow or stop cancer growth by blocking the survival pathways in lymphoma signaling including—the PKC-Beta and PI3K/AKT pathways. The trial is proceeding very well.

**OBR:** *How do you see Lilly and ImClone coming together and working to advance the pipeline and bring about more oncology products?*

**RG:** Acquiring ImClone strengthens Lilly's oncology portfolio and the combination expands Lilly's biotechnology capabilities. We see using the strength of ImClone, based on their bioproducts portfolio and combining that with Lilly's bioproducts, great commercialization history, and experience in cytotoxics to really become a major player in promoting value to patients, payers, and physicians. With both companies, there's incredible innovation. We both share the same culture—which is to deliver innovation to personalize cancer care and to develop different technologies for hard-to-treat cancers.

**OBR**

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