



I have spent more than 20 years in the biotechnology industry and have been able to lead the development of several life-saving and breakthrough drugs.

Ariad Pharmaceutical's **HARVEY J. BERGER, M.D.,** Provides Insights into the Intricacies of Building a Biotech Business

In his 20 years in the biotechnology industry, Harvey J. Berger, M.D., has witnessed huge leaps in terms of scientific research as well as the development of an industry. Today, as Founder, Chairman, and CEO of Ariad Pharmaceuticals, Dr. Berger has been the driving force in taking the company to the next level, which is to become a fully integrated oncology business.

Dr. Berger and his staff recently enjoyed a major breakthrough with a billion-dollar global collaboration with Merck & Co. to develop and commercialize Ariad's novel cancer drug, deforolimus (previously known as AP23573).

The Ariad/Merck deal, valued at almost \$1 billion, represents one of the most robust biotech collaborations of its kind and further validates the promise of Ariad's novel mTOR inhibitor drug deforolimus, which is about to enter the last stage of clinical testing in metastatic soft-tissue and bone sarcomas. Deforolimus also has potential as an anticancer therapy for breast, prostate, and endometrial cancers. Dr. Berger provides his insights on this exciting area of research and what the collaboration means to the company.

CREATING A BUSINESS

Why did you found Ariad?

BERGER: I had spent seven very productive years at

Centocor, one of the first-generation biotech companies, including time as president of the R&D division. I recognized that there were new opportunities in the development of small-molecule drugs that blocked cell-signaling pathways — a relatively new area of molecular cell biology. My goal in starting Ariad was to combine advances in organic chemistry, computational science, and molecular cell biology to discover novel small-molecule drugs. Subsequently, the field of chemical biology has evolved, blending the same concepts into a research discipline.

The name Ariad comes from Ariadne, a Greek myth in which the hero, Theseus, pursues and kills the minotaur, a mythical beast. The minotaur is at the center of a labyrinth and to get to and from the labyrinth safely, Theseus uses a spool of thread to mark out his pathway. Ariad's focus on cell signaling is much like the pathways in and out of the cell, which for years were referred to as the "black box" of the cell since little was known about these pathways.

BUILDING THE BUSINESS

How did you help bring about the collaboration with Merck?

BERGER: Over the past year, our scientific, medical, business development, and commercial teams met with their counterparts at more than a dozen major pharmaceutical and biotechnology companies and discussed our lead compound, deforolimus, and its broad medical and commercial potential in oncology. It was important that we play a leadership role in the global development and U.S. commercialization of our product, and we highlighted this in all of our partnering discussions. I played a key role in formulating the business strategy at the beginning and then was actively involved in the evaluation and negotiation of the term sheets with several companies. Eventually, we focused on Merck, because of its focus in the oncology market and its long-standing expertise with predictive biomarkers. We have a

CAREER Highlights

Harvey J. Berger, M.D., has been Chairman and CEO of Ariad Pharmaceuticals Inc. since April 1991. Before founding Ariad, Dr. Berger held a series of senior management positions at Centocor Inc., including Executive VP and President, Research and Development Division. He also has held senior academic appointments at Emory University, Yale University, and the University of Pennsylvania and he was an Established Investigator of the American Heart Association.

superb partner in Merck. The company's management is committed to building a world-class oncology business and managers recognized our need to build a successful and profitable oncology business as well. Most key decisions within the partnership will be determined jointly without either party having a final determination, which frequently occurs in this type of global collaboration. The partnership allows us to expand our clinical, medical, and regulatory groups and build a commercial organization as we approach product launch.

INTO THE FUTURE

What are your longer-term goals for Ariad?

BERGER: Our business strategy is clear: we are building a fully integrated oncology business. We will lead with deforolimus and follow with our pipeline of internally discovered oncology drugs. Our focus is exclusively on small-molecule, targeted drugs to treat or prevent cancer. Longer term, we will continue to bring novel cancer drugs from the laboratory to the clinic and marketplace.

As the founder of Ariad, my vision has been the driving strategic force behind the company since its inception, and with the help of a superb executive management team, we have blended the various scientific, medical, and commercial insights to create the organization we have today. As CEO, my biggest challenge is to oversee Ariad's transformation from an R&D company to a commercially oriented and profitable business over the coming years.

RESEARCH POTENTIAL

Which areas of research hold the greatest potential for breakthroughs?

BERGER: Scientific advances over the past decade in cancer research have highlighted the profound importance of understanding the molecular and genetic basis of malignant transformation of cells. The Cancer Genome Project offers great promise to expand our deep appreciation of the role of different genes and their protein products in cancer. These discoveries led to drugs such as deforolimus and our new multitargeted kinase inhibitor, AP24534, which will enter clinical trials in drug-resistant chronic myeloid leukemia by early next year. ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoices.com.

ARIAD'S Billion-Dollar Deal

Ariad and Merck have entered into a global collaboration to jointly develop and commercialize deforolimus, Ariad's novel mTOR inhibitor, for use in cancer. It is expected that deforolimus will enter into Phase III clinical development for the treatment of metastatic sarcomas in 2007. The agreement provides for Merck to make an initial payment of \$75 million to Ariad, up to \$452 million more in milestone payments based on the successful development of deforolimus in multiple cancer indications (including \$13.5 million for the initiation of the Phase III trial in metastatic sarcomas and \$114.5 million for the initiation of other Phase II and Phase III studies), and up to \$200 million more based on achievement of significant sales thresholds. In addition, Merck will pay at least \$200 million in contributions for global development, up to \$200 million in interest-bearing repayable development-cost advances to cover a portion of Ariad's share of global-development costs (after Ariad has paid \$150 million), and potential commercial returns from profit sharing in the United States or royalties paid by Merck outside of the United States.



● **Amber Runion**
INC Research QuickStart Specialist



It's Our People. It's Our Process.

As a global, therapeutically focused CRO, we understand that you need process to support your clinical development goals. The Trusted Process is our proven methodology that delivers predictably dependable outcomes.

Meet Amber Runion, a QuickStart Specialist, who works in the second phase of our Trusted Process. She has facilitated dozens of QuickStart camps, where she and her team use best practices from other sessions to hone a repeatable process. By tapping into the unique expertise of our QuickStart team, we reduce variability and execute your project as promised, from the start.

At INC Research, it's all about the process. Our Trusted Process means you experience trial excellence. Minimized risk factors. More informed and confident drug and device development decisions.

Visit us online at www.incresearch.com/start to view our video on
QuickStart™
Just one part of our **Trusted Process™**



Therapeutic Foresight. Trusted Results.™