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Pharmaceutical Executive

PLACE

*PHARM EXEC'S GUIDE TO THE
HOTTEST M&A TRENDS
AND OUR **TOP PICKS***

your

BETS

BY **JOANNA BREITSTEIN**, EXECUTIVE EDITOR

COUGAR BIOTECHNOLOGY

A bolt-on oncology pipeline

With a focused oncology pipeline, Cougar Biotechnology finds itself out in front with some promising molecules that could alter the cancer treatment paradigm. Skeptics caution against the hype that's surrounded its lead compound abiraterone (media have called it the next prostate cancer wonder drug), but for those willing to take a gamble could have a shot at the glory, even with additional therapies in the market.

Abiraterone is a small-molecule drug that inhibits the production of testosterone in all types of tissue—not just the testicles—through the androgen receptor, which moderates prostate cell growth. Small studies presented at ASCO and in the *Journal of Clinical Oncology* show that 48 percent of patients experienced at least a 50 percent decline in prostate specific antigen (PSA) levels, a marker of the disease, and 17 percent experienced PSA decreases of more than 90 percent.

The drug has recently entered Phase III testing—where trials are expected to enroll like “wildfire.” If all goes well, the company could submit an NDA to FDA by 2011.

“The doctors have been very excited about the activity they have seen,” says Howard Liang, Ph.D. of Leerink Swann. “If you look at the data, it has been consistent. The large size of the market, first-in-class [status], clear unmet medical need—all the factors make the drug really striking.”



Alan Auerbach, CEO,
Cougar Biotechnology

Certainly, there is desperate need. The American Cancer Society estimates that in 2008 there will be about 186,320 new prostate cancer cases in the United States alone. Another 28,660 men with advanced prostate cancer, who don't respond to treatment, will die. It is these men, who have failed on Taxotere, that abiraterone could help.

Analysts say there is room for multiple drugs in the large prostate cancer market, and the most likely competition is Dendreon's immunotherapy Provenge. The promise of that vaccine, which is currently once again in Phase III trials, caused prostate cancer patients to take to the streets and protest against FDA when it requested additional data. Dendreon expects results this October. If the data are consistent with what has been seen in the past, studies will show that Provenge extends life by 3.3 months. However, abiraterone has extended life by more than two years among clinical trial subjects.

Cougar is also part of an emerging crop of companies that are developing cancer drugs based on analogs of Vitamin D—more specifically its active metabolite calcitriol—because of its ability to inhibit cell proliferation and angiogenesis, and induce differentiation and apoptosis. Specifically, it has begun to test a drug called seocalcitol for prostate cancer. It's much further down the pike, but offers up some promising science—and certainly, some competition.

TRENDWATCH: VITAMIN D As if we needed more excuses to call in sick and go to the beach. Now, new science shows the promise of Vitamin D therapeutics in treating a broad range of conditions. “Someone was telling me that their trainer at the gym was going to Miami, and not bringing any sunscreen,” says Miller Tabak's Fundleyer. “The trainer said they wanted to soak up the Vitamin D—and you know when your trainer knows about Vitamin D, that's a hot area.”

VITAMIN D PIPELINE	COMPANY	COUNTRY	PHASE	INDICATION
ED-71	Chugai/Roche	Japan	III	Osteoporosis
2MD	Deltanoid	US	II	Osteoporosis
Leo80190	Leo	Europe	II	Psoriasis
BXL628	BioXell	Europe	II	Incontinence, BPH, Prostate cancer
CB1089	Cougar Biotechnology	US	I	Prostate cancer
Becocalcidiol	Collagenex	US	II	Psoriasis
CTA018	Cytochroma/ Mitsubishi Tanabe	Canada	II	Secondary hyperparathyroidism
inecalcitol	Hybrigenics SA	France	II	Prostate cancer
MN01	Marillion Pharma	US	IND	Prostate cancer, breast cancer

SOURCE: Company Web sites, accessed August 2008