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Pharma Ramps Up Research On Vaccines To Treat Cancer

BY PETER BENESH
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On Wednesday, pioneer prostate-cancer vaccine company **Dendreon**^{DNDN} reported sales about 20% below consensus for its 2010 third quarter. Instead of the anticipated \$24 million in third-quarter revenue from Provenge, a vaccine to fight prostate cancer, the number was just over \$20 million.

Not a disaster, analysts say. After all, the company got regulatory approval only in May. Most held to their view that shares are a buy because worldwide potential is so strong.

Also, **Bristol-Myers Squibb**^{BMY} announced Tuesday that the Food and Drug Administration was delaying its decision date on Bristol's ipilimumab, a vaccine for melanoma, by three months, to March 26, 2011. The FDA wants more data.

Both products are cutting-edge technology. They're called vaccines, but that's confusing, says Michael Becker, a former biotech executive who now runs his own consulting firm, MD Becker Partners. People usually think of vaccines as preventative, like flu shots and the famed Salk vaccine for polio.

But these new vaccines aim to trigger the body's own immune system to recognize cancer as alien and fight back. Economics explains why the focus is on treatment rather than prevention, Becker says.

He spoke with IBD.

IBD: Let's start with that nomenclature problem.

Becker: We do use the term vaccine imprecisely. It can be either preventative or therapeutic. It's a source of confusion for the public and for the investors who support these companies. We should use immunotherapy for treatment and vaccine for prevention.

Preventative is always better than trying to treat after the disease has taken hold. The big-

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- Founder, president and chief executive
- 42 years old
- Attended

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■ Of note: Former president and chief executive, 2002-07, of Cytogen Corp.

ger benefit to the patient is preventative.

IBD: Which has greater market potential?

Becker: There are more patients you can treat prophylactically — that is, where you're trying to prevent the condition from occurring in the first place. The patient number is much larger when you talk about prevention, but the price you can charge is less.

Prevention means more patients at lower cost for the drug while immunotherapy means fewer patients at much higher cost for the drug.

IBD: So preventative vaccines become commodities?

Becker: Correct. When you make a prophylactic vaccine, the question becomes, "How much can you make and how fast can you make it?"

IBD: And how much is biopharma focused on vaccines for prevention of cancer?

Becker: I can't think of any preventative vaccine in clinical trials right now. **Merck's**^{MRK} Gardasil, and **Cervatrix**, from **GlaxoSmithKline**^{GSK}, for human papillomavirus aren't cancer vaccines. They aim at the virus that can cause cervical cancer.

Everybody's working on treating the disease.

IBD: Because?

Becker: It's not because Big Pharma's being cheap or trying

to cut corners. The type of study you need to do to show prevention is a very long study. That's not a financial reality for any company.

Say you give a vaccine to every man 50 years old in the hope of preventing prostate cancer. That's many millions of men.

Prostate cancer can take years to develop. Think about how big and how long that clinical study would be.

And many men won't develop prostate cancer, but even the men who do will go on to various types of treatments and, on average, a prostate cancer patient lives for five years with today's conventional therapies.

The bottom line is that to do the types of studies we would want to see, there's not enough money in biopharma to do it.

So we need shorter development periods, and that leads us to immunotherapy drugs that can increase survival by months rather than preventative drugs that would give us years.

IBD: Staying with immunotherapies for cancer, what could speed them along?

Becker: It's almost an issue of recycling. There are many good vaccines that have failed because they weren't tested in the right clinical setting.

They're now being re-explored in new clinical studies. That seems a low-risk, high-reward proposition.

Because of the earlier research, these can move right into late-stage trials of the right type. A great example is a vaccine aimed at pancreatic cancer.

A vaccine that did not show efficacy in pancreatic cancer is now being tested in prostate cancer and is the leading challenger to what will likely be the next prostate cancer vaccine approved, and that's a drug being investigated by Ba-

varian Nordic of Denmark that's about to start a pivotal phase three trial.

IBD: Who else is doing what?

Becker: GlaxoSmithKline is working on a lung cancer vaccine. It's in a pivotal trial with data expected in 12 to 24 months or so. It's the largest lung cancer study ever undertaken.

Bristol has its now-delayed melanoma immunotherapy, ipilimumab, which is so hard to say, everyone just calls it Ipi.

Merck is partnered with a company called **Inovio**^{INO} in a cervical cancer vaccine.

Pfizer^{PFE}, interestingly, just walked away from a cancer vaccine partnership they had with **Celldex**^{CLDX} in a brain cancer vaccine. Pfizer returned the rights, saying it had "re-prioritized" its portfolio.

IBD: You've been talking mostly about big pharmaceutical companies doing the research.

Becker: Even immunotherapies require long-term studies. That's tough for emerging biotech to fund, especially in the current economic climate.

An emerging biotech can't afford the five- or 10-year studies needed to bring a cancer immunotherapy to market.

IBD: Dendreon did manage it, though. How would you rank the significance of its immunotherapy, Provenge, even though sales have not skyrocketed?

Becker: The approval of Provenge is a huge positive because it proved the concept of stimulating the immune system is viable.

IBD: It extends life by a median of about four or five months and costs almost \$95,000.

Becker: It isn't fair to look just at median survival and ask, "What's the benefit of four months?"

Some patients will do a lot better, and some not as well. For some, the survival difference can be 12 months or even two years.

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