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PHARMACYTE BIOTECH

Celgene May Also Want to Take Notice of PharmaCyte Biotech

BONITA, CA -- (Marketwired) -- 07/24/15 -- A recent deal between Celgene and Juno Therapeutics is just a microcosm of the mindset that may ultimately drive a similar deal between it -- or a competitor -- and PharmaCyte Biotech (OTCQB: PMCB).

Last month, Celgene handed $1 billion to small biotech developer Juno Therapeutics for a 10 percent stake in the company plus a piece of whatever revenue Juno's CAR-T cancer therapy might produce if and when it's approved. It's a big bet from Celgene to be sure, in that its CAR-T (chimeric antigen receptor T-cell) therapy is only in Phase 1 clinical trials, and the company has little else in its pipeline as exciting as that R&D.

And yet, Celgene's interest in new cancer drugs (and a willingness to pay significant amounts for them) is nothing unusual for the company or its peers. Indeed, the last couple of years have brought with them a tidal wave of mergers and acquisitions within the pharmaceutical world. Many of the largest of those acquisitions are ultimately aimed at bringing new cancer drugs into the fold... even therapies that are years away from possibly hitting the market.

In May, Eli Lilly entered collaborations with BioNTech to develop cancer immunotherapies. In March, Johnson & Johnson announced it would be buying Pharmacyclics primarily for its oncology drug Imbruvica, which some say could produce annual sales in excess of $3 billion once it hits full stride. Many more oncology-related deals were forged before that.

In the aggregate, all the M&A within the Bio-Pharma space -- and within the Oncology space in particular -- are the new norm. Rather than develop a drug, it's now cheaper and easier just to buy one, or even speculate on one as Celgene did in its deal with Juno. And it's unlikely this is a mindset that will change anytime soon. If anything, this trend is still accelerating, which means all small up-and-coming cancer drug developers are potential buyout targets, depending on the strength of its pipeline.

To that end, and in light of the Celgene deal, one of these smaller biotech firms comes to the forefront as a potential acquisition target -- PharmaCyte Biotech.

PharmaCyte Biotech is developing treatments for both cancer and diabetes using a platform technology called Cell-in-a-Box®. The encapsulation technology is made up of genetically modified live cells that are capable of activating a chemotherapy prodrug in the case of the company’s pancreatic cancer treatment, and cells capable of producing insulin in the case of PharmaCyte’s diabetes treatment.

The manufacturing process begins with the mix of live cells and a polymer, which are sent through a droplet-forming machine and into a small vat of a proprietary polymer. When the two polymers join, a membrane is formed, creating a spherical shell about the size of the head of a pin with the live cells inside. These cells function normally in the tiny capsules,

which have a porous shell that allows nutrients to get inside the capsules to feed the cells while also allowing waste products out of the capsules. The cells inside remain safe from immune system attacks, as the capsule's pores are too small for the body's immune system to reach the cells inside.

The applications of such a technology are virtually unlimited, but the bulk of the work done so far with Cell-in-a-Box® has taken aim at pancreatic cancer and the rekindling of a less-used anticancer prodrug called ifosfamide.

Ifosfamide isn't a new drug, and it's not the standard go-to treatment for pancreatic cancer either. That honor belongs mostly to gemcitabine, and more and more so when it's combined with Abraxane®... but not necessarily for the reason one might assume.

Ifosfamide in its active form is usually delivered intravenously and then activated or catalyzed in the liver. The process works, but because of the drug's short half-life, much of the drug never makes it to the pancreas in an intact form; instead, breaking down in the body before reaching the pancreatic tumor. To deliver a dose big enough to make a dent in a pancreatic tumor, side effects are almost a given. But, ifosfamide requires such a large dose to be effective that the side effects can be nearly intolerable.

The Cell-in-a-Box® approach circumvents this inefficient form of delivery by inserting encapsulated P450-producing (an enzyme that activates ifosfamide) cells very near the tumor itself, which means ifosfamide isn't activated until it's at or near the pancreatic tumor, ensuring maximum delivery of the drug with a minimum dose. Ergo, fewer, if any, side effects are found, and the otherwise unusable-but-effective drug becomes a treatment option again.

And yes, PharmaCyte Biotech's treatment has demonstrated measurable efficacy with this approach.

In a phase 1/2 clinical trial examining the benefits of the Cell-in-a-Box® technology combined with low doses of ifosfamide versus the results gemcitabine would be able to achieve alone, the PharmaCyte approach improved the median survival time from 28 to 44 weeks. Equally impressive is the fact that the number of one-year survivors increased from 18% to 36% of the study's patients. The next stage of the trial will pit ifosfamide against the gemcitabine/Abraxane® combination, which is arguably the preferred therapy among oncologists at this time... at least for now.

Care to guess who owns Abraxane®? It's Celgene, which makes something Motley Fool contributor Todd Campbell said of the Celgene/Juno deal worth mulling over. He wrote:

"... Celgene's decision to cozy up with Juno Therapeutics wasn't just about betting that JCAR015 or other drugs succeed. It was also about protecting Celgene's multi-billion-dollar revenue stream.... The majority of CAR-T research targets indications that contribute a big chunk of Celgene's expected $9 billion in annual revenue this year."

If Campbell is right -- and he probably is -- it's not out of the realm of possibility that sooner or later Celgene will be forced to look at PharmaCyte Biotech Inc. as a potential acquisition, since PharmaCyte poses a big threat to Abraxane® sales.

On the surface it may seem like a minor threat -- PharmaCyte is only taking aim at pancreatic cancer, but Abraxane® is approved for multiple indications. The Cell-in-a-Box® technology is very versatile though, and is currently being studied as a treatment for symptoms related to all solid abdominal cancers, as a means to treat diabetes, as well as brain cancers. If the company can make ifosfamide outperform the gemcitabine/Abraxane® combo on the pancreatic cancer front, how long will it take PharmaCyte to start using the same platform technology to dethrone Abraxane® on other cancer fronts?

Of course, it wouldn't have to be Celgene doing the buying. A myriad of other Bio-Pharma names may also want to try Cell-in-a-Box® as a means to up-end a variety of category-leading cancer drugs. Most oncology drug makers should be at least a little worried about the disruptive technology that has already threatened to shake things up within the pancreatic cancer arena of the oncology market.

Clearly it's only a speculative idea, but if Celgene was willing to shell out $1 billion just on the mere chance that CAR-T therapies from Juno could pose a threat to Abraxane's® sales, it's not out of the question to think that Celgene or another cancer player isn't using the same mindset with regard to PharmaCyte.

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