# Avastin Ousted by FDA for Breast Cancer, Sunshine Biopharma Gears-Up for Clinicals

11/28/2011 [ACCESSWIRE] It was only about a week ago that the U.S. Food and Drug Administration revoked the approval of Avastin® (bevacizumab) as a treatment for breast cancer. This is not the end of the world for the Genentech, who was acquired by the Roche Holdings (OTCQX:RHHBY) for $46.8 billion in March of 2009, drug as it still retained its indications for colon, kidney, lung and brain cancer. The revocation did, however, increase awareness for other breast cancer treatment candidates coming down the pipeline.

Researchers have been searching for years to find an alternative, complement and competition for AstraZeneca's (NYSE:AZN) Nolvadex® (tamoxifen), a popular breast cancer therapy in use for three decades. Recently, Dr. Jeffrey Tobias of University-College Hospital, London, commented on potential serious heightened risks associated with tamoxifen, including cancer of the womb lining, "This is a real concern in early breast cancer when patients are generally taking the drugs for up to five years." Dr. Tobias is an investigator in clinical trials of Arimidex®, an aromatase inhibitor which shuts down the body's sometimes cancer-promoting oestrogen supply. In all fairness to tamoxifen, most anti-cancer drugs carry potential for serious side effects, but the benefits generally outweigh the risk.

More recently, the hunt has also been for an alternative to Roche's Herceptin® (trastuzumab), a drug proven to significantly extend the lives of HER2 (human epidermal growth factor receptor-2)-positive metastatic breast cancer patients. While Herceptin® has shown a strong therapeutic benefit, it only targets HER2-positive patients and does not address Top2 (topoisomerase II)-positive patients, the second enzyme widely-known to be associated with aggressive forms of cancer. Etoposide drugs marketed as Etomedac®/Eposin by Medac and Bristol Meyer Squibb's (NYSE:BMY) Etopophos® and Vepesid® are common treatments to exploit Top2 in cancer patients.

Sunshine Biopharma (OTCBB:SBFM) is looking to fill the gaps in breast cancer therapies with their flagship compound Adva-27, a small molecule that targets and inhibits Top2.

Pre-clinical trials are now behind Sunshine Biopharma with strong data supporting further development of Adva-27. Research to date has shown the compound to be 16-times more effective at killing multi-drug resistant breast cancer cells than Etoposide. Importantly, Adva-27 is unaffected by P-Glycoprotein, the enzyme responsible for making cancer cells resistant to anti-tumor drugs, and is independent of Cytochrome P450, a mechanism that is less likely to produce toxic intermediates. An excellent pharmacokinetic profile has been generated so far in pre-clinical research as well. Adva-27 has potential for multiple indications, but initial clinical trials will focus on multi-drug resistant breast cancers.

According to the Breast Cancer Organization of the USA, it is estimated that more than 260,000 new cases of breast cancer were diagnosed last year. The dreaded disease has rightfully never slipped from the spotlight, but has garnered stronger attention again with the latest news about Avastin®. By targeting drug-resistant cancer strains and outpacing Etoposide, Sunshine Biopharma's Adva-27 is right in the mix with other anti-cancer drugs in development. Just as Herceptin® revolutionized HER2 therapies for breast cancer – and generated nearly $7 billion in 2010 sales alone – Sunshine is looking to do the same with its Top2 drug in the future.



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