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February 15, 2019

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month, I covered "Conducting the Marketing/Business Due Diligence Early in Product Development Can Avoid Issues and Problems Later in Development and Post Launch." If you missed last month's article, click here to read it. This month we'll cover "Thinking Outside the Box in Fighting Cancer."

Read on to learn more about this topic and other current news. The next newsletter will be published on March 15th, 2019.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on the link below.

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Planning Consultant
BioMarketing Insight

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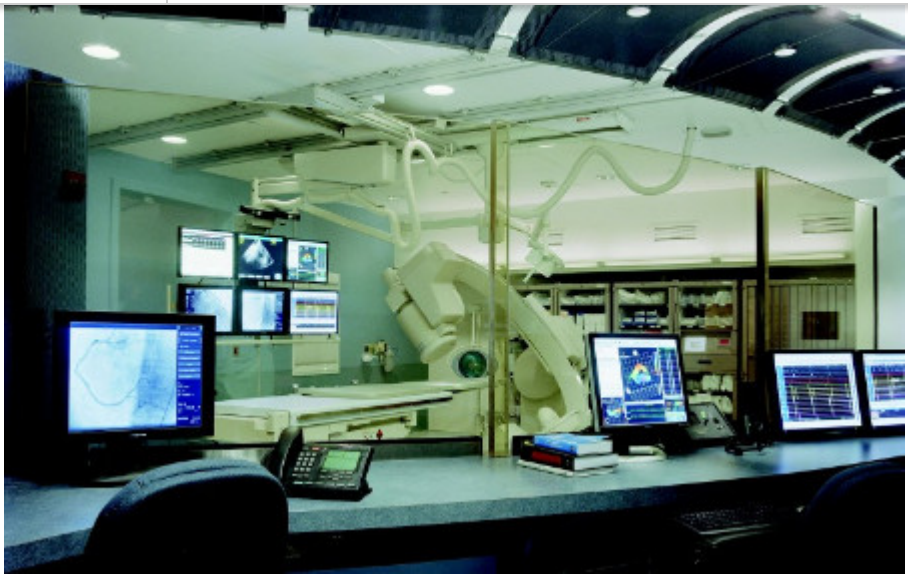

Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product or looking to grow your business, contact me for an appointment.

For more information on our services, click on the links below:

Product Development
Market Development
Marketing Strategies

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I am pleased to announce that my article entitled "Updates in Solving the Mystery of Alzheimer's Disease Pathology" was published in the International Journal of Clinical Pharmacology & Pharmacotherapy. This commentary reviews the "Updated Proposed timeline of biomarker abnormalities leading to cognitive impairment" and the involvement of both beta amyloid clearance and plaque, and tau clearance and tau-mediated neuronal injury and dysfunction. To read the article, click here.

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Why Our Microbiome is Important to Our Physiology and Diseases

I am pleased to announce that my article entitled "Why Our Microbiome is Important to Our Physiology and Diseases" was published in the International Journal of Clinical Pharmacology & Pharmacotherapy. This article reviews the results of the Human Microbiome Project and the factors that affect our microbiome in relation to our healthy state and dysbiosis or disease state. To read the article, click here.

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Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell Design Be Made to Cure All Types of Cancers and Will It Be Covered?

I am pleased to announce that my article on "Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell (CAR-T) Design Be Made to Cure All Types of Cancers and Will It Be Covered?" has been published in Journal of Pharmaceutics. This article reviews the mechanism, design and administration of CAR-T cells, and whether payers will pay for this new technology. To read the article, click here.

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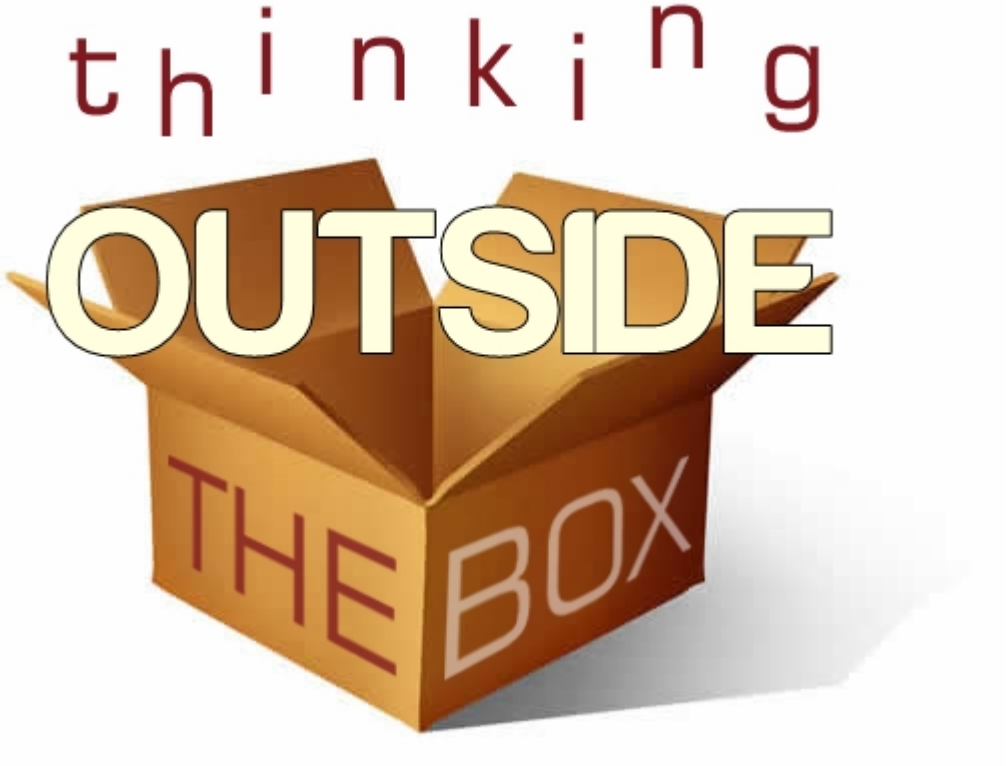

Scientists have been working to develop drugs that can either stop the progression of cancer or result in the patient being cancer free with drugs such as Immuno-oncology (IO) drugs for years and have found success with some drugs while others have failed. But cancer is very complex as there can be subsets of a subset within specific type of cancer making it difficult to understand how they survive and evade cancer drugs.

Some scientist have looked outside of the traditional research and drug development in discovering some interesting facts. I will cover four (4) areas researchers are working on:

1) Scientists from the University of Basel have discovered that when they combine two FDA-approved drugs, GlaxoSmithKline's diabetes drug Avandia (rosiglitazone) and Novartis' cancer treatment Mekinist (trametinib), that breast cancer cells in mice transformed into fat cells and prevented the tumors from growing and spreading. "As far as we can tell from long-term culture experiments, the cancer cells-turned-fat cells remain fat cells and do not revert back to breast cancer cells," said Gerhard Christofori, a professor of biochemistry at the University of Basel.

The key to the success of the Swiss scientists' experiment was their ability to exploit a developmental phase called epithelial-mesenchymal transition where the cancer cells become more like stem cells but it can also promote metastasis.

When researchers administered Avandia and Mekinist to mice that had human breast cancer cells implanted into them, the drugs slowed the growth of the primary tumors and prevented the cancer from spreading.

The Basel researchers believe that the combination of Mekinist and Avandia forces enough cancer cells to differentiate into fat making the primary tumor no longer able to resist conventional chemotherapy. Their next step is to use this same combination approach along with chemotherapy to see if it works in other cancers as well.

2) Interleukin 2 (IL-2) have been used to treat metastatic renal cell carcinoma and melanoma but as a last resort due to its toxic side effect profile. Scientists at the University of Washington have used computer programs to design a new Interleukin 2 protein called Neo-2/15 that has the therapeutic properties of IL-2 but doesn't trigger toxic side effects.

"People have tried for 30 years to alter IL-2 to make it safer and more effective, but because naturally occurring proteins tend not to be very stable, this has proved to be very hard to do," said Daniel-Adriano Silva, UW Medicine's Institute for Protein Design (IPD) in Seattle. "Neo-2/15 is very small and very stable. Because we designed it from scratch, we understand all its parts, and we can continue to improve it making it even more stable and active."

To design a cancer-fighting protein that would not cause toxic side effects, the researchers used a computer program called Rosetta to design their protein surfaces to bind to and activate IL-2 receptor beta and gamma, but not the IL-2 receptor alpha, which is part of the harmful cells.

UCSF
University of California
San Francisco

3) Researchers at University of California, San Francisco have found a way to successfully prevent proteins that stimulate cancer-driving genes including those that shield tumors from the immune system, from being built in the first place.

genetic material is transformed into proteins which in turn slows the tumors' rampant growth in a new mouse model of liver cancer that blocks the cancer's ability to evade the immune response using a genetic approach and a drug currently in clinical trials.

"This is a new avenue for liver cancer intervention," said Davide Ruggero, PhD, an expert on how cancer cells corrupt normal protein synthesis to spur their own growth and survival. "There is a particular subset of proteins, more beneficial to cancer cells than to normal cells, called the 'cancer proteome.' Once we know the mechanisms by which cells shift to favor that proteome, we can develop drugs to target it."

This new research from Ruggero's lab offers an alternate strategy to abolish the cancer's defenses where checkpoint proteins won't need to be blocked with inhibitors if they are never built in the first place.

Duke UNIVERSITY

4) MMPs (matrix metalloproteinases) inhibitors were disregarded for the treatment metastatic cancer because they failed in clinical trials. However, researchers at Duke University have discovered why MMPs failed which could lead to new treatment regiments for combination therapy in metastatic cancers.

MMPs (matrix metalloproteinases) are enzymes that dissolve the outer membranes of cells that are vital for cancer cells to escape their point of origin and invade healthy tissues elsewhere in the body. So why weren't inhibitors of MMPs successful in stopping cancer from spreading in human trials?

Duke researchers discovered that invasive cells can survive and spread without MMPs by building a “battering ram” similar to a protrusion that busts its way in and out of cell walls when they studied the C. elegans worms.

Duke biology professor David Sherwood, Ph.D., describes it as normal worms invade cells by moving through a narrow opening "kind of like the escape tunnel in 'The Shawshank Redemption'". "But in knockout worms it's more like the Kool-Aid Man when he busts through walls."

mitochondria, the energy centers in cells to power their attack. Inhibiting a mitochondrial gene could prevent invading cells from bashing through other cells' walls.

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Closing Thoughts

Cancer is such a complex disease and although scientists have made great strides in some types of cancer, there are many cancers that are still devastating. Today, scientists have the tools to understand cancer better in order to develop new drugs such as immuno-oncology (IO) drugs. However, it seems that they still have a long way to go.

It is wonderful that scientists as the ones mentioned above are taking a different approach to understanding cancer in order to develop new drugs for cancer. Their approach in understanding the mechanism of cancer by answering why drugs have failed in the past as demonstrated with scientists at Duke University and UC San Francisco should be a core focus.

Making the connection in experimenting with drugs not related to cancer such as the treatment regiment with Avandia (diabetes) and Mekinist is not the first choice one would expect to work on breast cancer. But as one thinks about it, cancer cells thrive on glucose and diabetes is a risk factor for liver, pancreas, endometrium, colon and rectum, breast, and bladder cancer. Now researchers are drawing a firm conclusion that diabetes raises a person's risk of developing cancer because overly high levels of blood sugar may damage a person's DNA, thereby heightening their risk of cancer.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition and economic value of your product, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.

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