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January 15, 2020

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Happy New Year! This is not only the start of a new year but a new decade. I look forward to this new decade and the many advances it will bring to our industry.

The last topic I cover was "Regulatory Updates: Some Good News and Additional EU Requirements" If you missed this article, click [here](#) to read it. This month we will cover "New Approaches to Alzheimer's Disease."

Please read on for other current news in the Table of Content below. The next newsletter will be published on February 15th, 2020.

We encourage you to share this newsletter with your colleagues by using the social

Please email [me](#), Regina Au, if you have any questions, comments, or suggestions.

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:

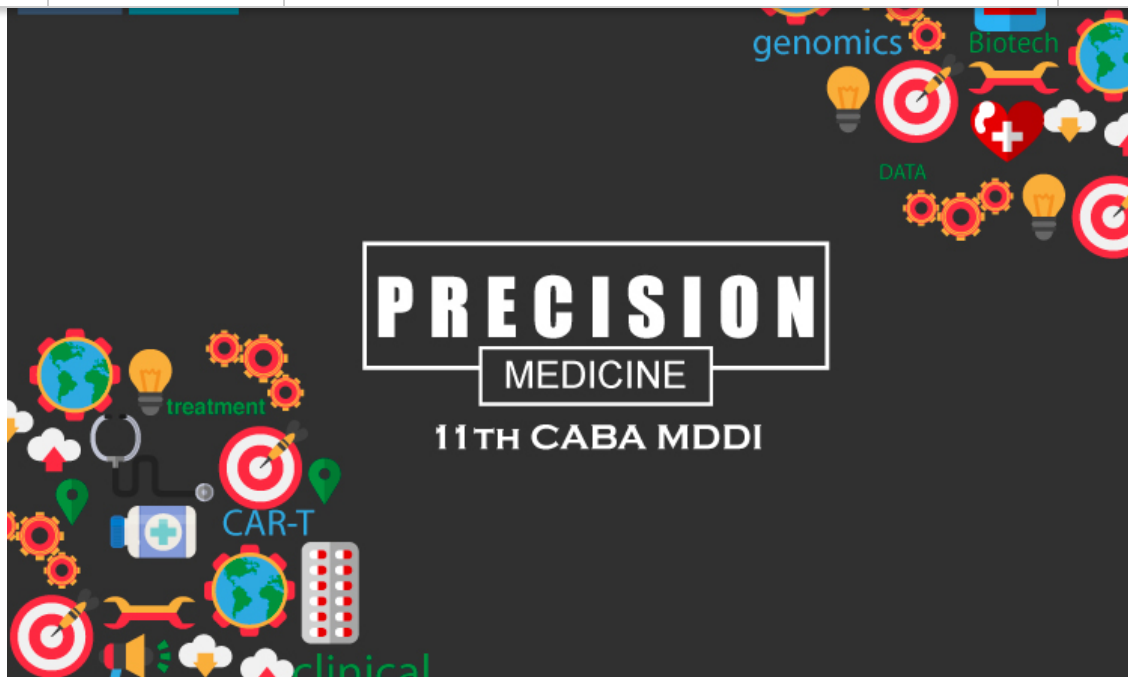
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### 11st CABA Medical Device and Diagnostics Innovation Symposium (MDDI)

I am pleased to announce that I am a panelist at the MDDI Symposium on Saturday, December 14, 2019 at the Conference Center at Waltham Woods, 860 Winter St, Waltham. The panel discussion is on "Precision Medicine in Medical Device." To find out more, click [here](#).

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### Asian American Women in Leadership Conference

I am pleased to announce that I conducted a workshop titled "Develop Your Leadership

the conference, click [here](#).

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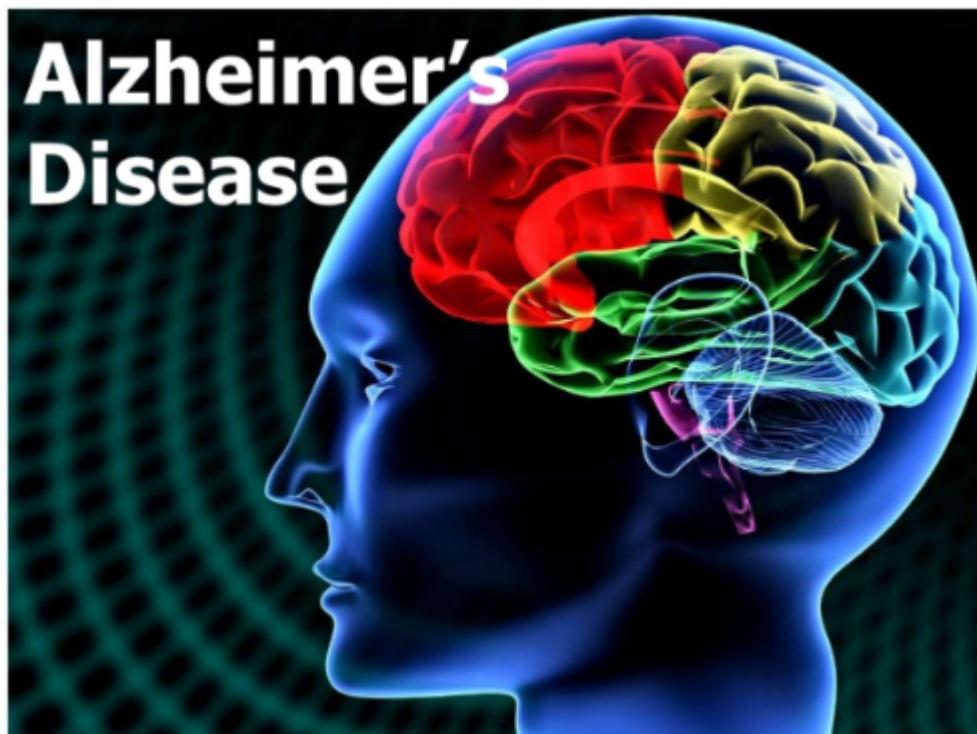
# BioProcess International

## Why Conducting Marketing Due Diligence Early in Product Development Is Important

I am pleased to announce that my article entitled "Why Conducting Marketing Due Diligence Early in Product Development Is Important" was published in the BioProcess International Magazine. To read the article, click [here](#).

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### New Approaches to Alzheimer's Disease

Scientists have researched and conducted clinical trials on Alzheimer's Disease (AD) for over three decades, but unfortunately, no drug has made it to the market in the US. AD is

accumulation as to the cause of AD with a number of clinical trials being conducted in this area.

Today, other scientists have taken a different approach to the cause of AD and I will be discussing three such approaches that hopefully will shed some light as to the cause and possible diagnosis and treatment for AD.

### **Approach 1:** Blood Test - Exosome marker, a key indicator of AD

Researchers from [Nagoya City University](#) and other institutions have discovered that the number of exosomes which are vesicles that mediate intercellular communication are reduced in Alzheimer's patients. Hypothesizing that a decrease in a protein called flotillin, a marker of exosomes, in the blood maybe a key indicator of the disease.

"Flotillin detected in less than a drop of blood enables a diagnosis of Alzheimer's disease and mild cognitive impairment at a stage prior to the disease," said Prof. Makoto Michikawa of Nagoya City University.

When the team conducted PET scans on Alzheimer's patients, they discovered that as beta amyloid are depositing in the brain, the number of exosomes secreted from nerves and other cells are reduced, resulting in a decline of flotillin levels in the cerebrospinal fluid and serum. These results demonstrate that serum [flotillin level](#) can serve as one of the blood markers for estimation of brain amyloid deposition and early diagnosis of AD.

### **Approach 2:** Fat and sugar metabolism in the brain

John Didsbury, CEO of [T3D Therapeutics](#) said the company's experimental therapy "works to overcome aberrant glucose (sugar) and lipid (fat) metabolism in the brain that is inherent in AD. This dysfunctional metabolism causes protein mis-folding which in turn leads to plaques, tangles and inflammation."

Didsbury said: "We believe T3D-959 has the potential to be Alzheimer's disease remedial, to either slow, stop, or even reverse the course of disease as a single drug therapy."

### **Approach 3:** Altering gut microbiomes

A new plant-based drug called [GV-971](#), a sodium oligo-mannurarate derived from brown algae has been approved in China for the treatment of AD. [Greenvalley](#) Pharmaceutical, a Chinese biotech claims their drug improves cognitive function in Alzheimer's patients by altering their gut microbiomes. In mouse studies, this approach reduced inflammation in the brains of rodents engineered to develop Alzheimer's-like pathology. In their original mouse studies, it suggested that an imbalance in the gut's microbiota produces immune

that reduced the accumulation of [neuroinflammatory](#) cells.

The clinical trial has not yet been published but Chinese regulatory have approve the drug with the condition that the company gather additional safety and efficacy data, as reported by *ScienceInsider*.

There has been mixed view from AD experts. "I think it's fascinating, and if it's true that [the effects are happening] through the microbiome, that's fantastic," Sangram Sisodia, a neurobiologist at University of Chicago in Illinois who has studied the impact of the microbiome on Alzheimer's disease in mice, he told *ScienceInsider*. But he also wants to see more evidence.

"We're still cautiously optimistic," Rebecca Edelmayer, director of scientific engagement at the Chicago-based Alzheimer's Association, she told *ScienceInsider*. "I think we need to really understand for sure what kinds of changes are occurring through a medicine like this and how they actually relate to a disease process."

Jeffrey Cummings, an Alzheimer's researcher at the University of Nevada in Las Vegas, who is advising Green Valley, says that GV-971 doesn't yet meet the criteria for approval in the US. But Green Valley plans to initiate a multicenter global phase III clinical trial with sites in the US, Europe, and Asia in early 2020 to gather data needed to support regulatory approval in other countries.

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Closing Thoughts



our understanding of this disease. It seems that there is no single mechanism similar to a single mutation that causes this disease if one examines the pathology of AD. It appears that once there is amyloid, tau or alpha synuclein accumulation, the disease has reached a point where one can't halt the progression of this disease.

Which means according to scientists, AD has to be diagnosed 10 years before symptoms and protein accumulation. In order to achieve this, scientists need to discover the relevant biomarkers that definitely diagnosis pre-AD and the example of exosome flotillin protein biomarker is promising. Then we can start to figure out how to prevent accumulation of these harmful proteins.

How scientist can halt the progression of AD or improve cognitive function will be a multipronged approach if metabolism affects protein misfolding for AD. The gut microbiome also plays an important part in human metabolism such as breaking down food or delivering vitamins that humans can't product. One could also theorize that through symbiosis our gut microbiome is also preventing inflammation.

Today, complex diseases are usually treated with a cocktail of drugs as in the case of most types of cancer, Hepatitis (B and C) and HIV. The advantage of using a cocktail, which is a paradigm shift from monotherapy is to pursue the delicate balance between the optimal dosage for efficacy yet eliminate unwanted off-target side effects.

I am looking forward to the advances this new decade will bring.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 781-935-1462 or [regina@biomarketinginsight.com](mailto:regina@biomarketinginsight.com).

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