July 15th, 2023

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Our 2nd Annual AAPI Heritage Festival held on Saturday, May 20th, 2023 went well despite the heavy down pours. Our Festival made the front page of the local Daily Times Chronicle. Click on this link to see highlights of the festival.

In this month's newsletter I will cover "FDA Approves Alzheimer's Drug LEQEMBI®, Will Physicians Rush to Prescribe it?" You can find my article under the Table of Content and click on the link.

If you missed the last months newsletter on "The Impact of Climate Change on Your Health" click here to read the article.

enjoy the music from the Berklee School of Music in their song "What the World Needs Now," other inspirations and ending with Celine Dion and Josh Groban with "The Prayer".

Please read on for other current news in the Table of Content below. The next newsletter will be August 15, 2023.

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 "join my email list" link below.

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
BioMarketing Insight

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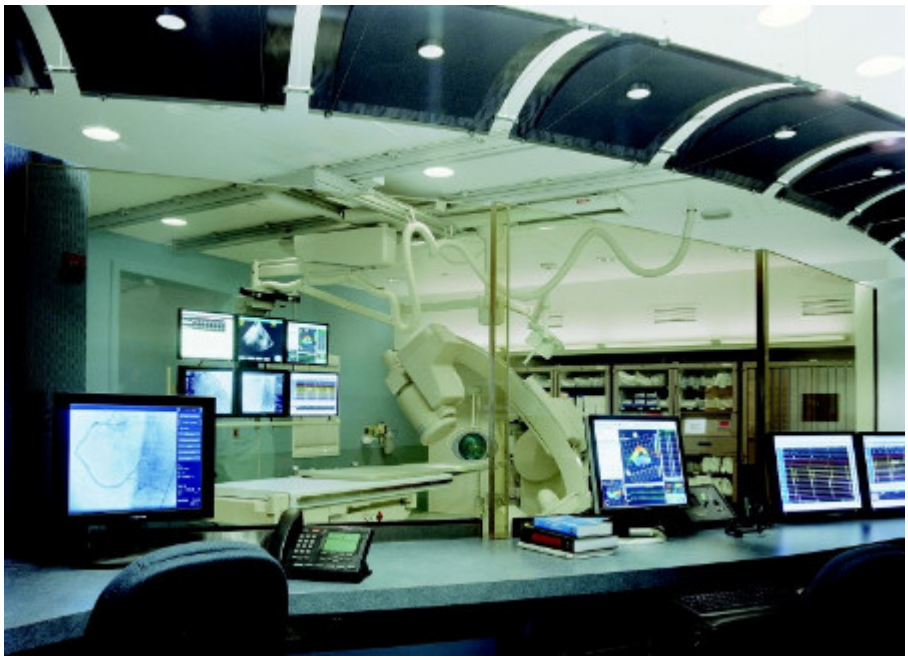
Join my mailing list



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

Scenario Planning - for more information, email me.

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Recap of the AAPI Heritage Festival - Saturday, May 20th, 2023

The Asian American Pacific Islander (AAPI) Heritage Festival was a success in celebrating AAPI Heritage Month with both the Asian and nonAsian communities. This celebration was to build awareness and educate our community on the various cultures and contributions the different Asian and Pacific Islanders ethnic groups have brought to enrich our American History.

Our Festival made the front page of the Daily Times Chronicle. See the article and pictures of our speakers, musicians and performers. In addition, we had our "Contributions AAPI Have Made to American History" Exhibit on display in the lobby and continued on into the program room. More pictures will be revealed next month.

Guest Speakers: Massachusetts State Representative Vanna Howard
Mayor Scott Galvin of Woburn
Special Guest Musician: Kevin So
Guest Musician: Entian Lee, Chinese Zither
Guest Performers: Swasti Bhargava & Aanvi Bhargava, Ekam Boston
Anvee Gudipati, Sreshta Mahavadi, Ekam Boston

Daily Times Chr

Home Delivery $1.00 FRIDAY - May 26, 2023 Home

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City Council seeks more info on fil

By PATRICK BLAIS

WOBURN - The City Council wants to consult with the city engineer's office and other department head managers before allowing a Lowell Street landowner to spread out fill in a low-lying depression.

During the elected officials' latest gathering in City Hall, Boxford resident Valentino Tocci Jr. explained that he is looking to bring in more than 100 cubic yards of fill to the back yard of a two-family property at 2 Lowell St., which sits in the city's Central Square area by Main Street.

The council, looking for additional details about the total volume of soil and rocks being brought in and

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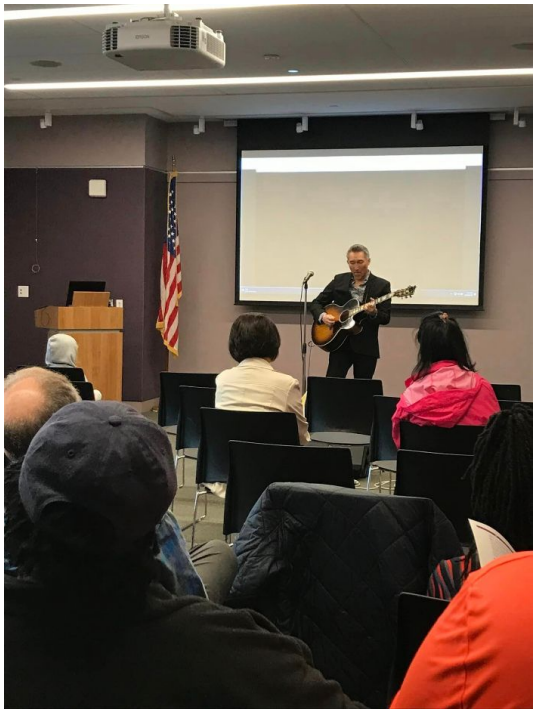
THE ASIAN AMERICAN PACIFIC ISLANDERS HERITAGE FESTIVAL was held at the Woburn Public Library with many posters describing the contributions made to American history. Volunteers and participants in the AAPI Heritage Festival included (l-r) Katherine Jiao, Vicky Wu, AAPIEC Inc. President Regina Au, and Ekam USA-Boston Chapter Director Nagasree Chakka. Some of the entertainment were dancers and musicians inside the library along with food vendors set up outside in the library's parking lot . (KAPAndrewsPhotos)

Board adopts - Burlington middle school ...




Asian American
and Pacific Islander
HERITAGE FESTIVAL

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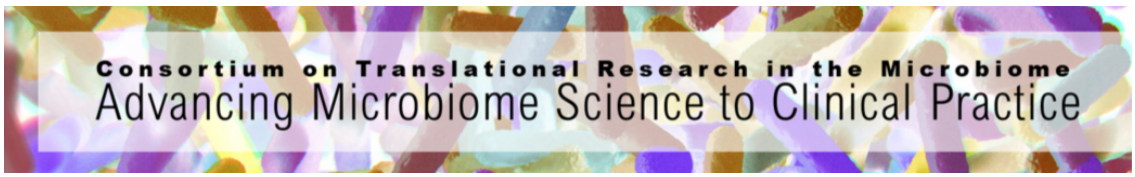

General Guidelines to Launch and Build a Clinical Trial Using Microbiome Products in an Era of Personalized Medicine.

I am pleased to announce that I was a speaker at the Westchester Biotech Project for Consortium on Translational Research in the Microbiome on November 11th, 2021. The Topic: General Guidelines to launch and build a clinical trial using microbiome products in an era of personalized medicine. My presentation was on " How to Launch and Market a Successful Microbiome Product: Five Major Considerations". For more information on this event, click here. This webinar it will be available next month, so check back here.

For more information on Westchester Biotech Project and future webinars, click here.

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Fresh Thinking in the Next Normal

I am pleased to announce that I was a speaker at the Institute of Management Consultants event on "What Will the “Next Normal“ Be for Productivity, Motivation and Retention of Employees? Four Things Employers Need to Consider." on July 20th, 2021 at 2 pm. For more information and to register click here.

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Inspirations

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.

We Will Get Through It Together

Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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Lioness
FOR THE FEMALE ENTREPRENEUR

One Biotech Executive's View on the COVID-19 Vaccine

I am pleased to announce that my article on the COVID-19 Vaccine was published in Lioness Magazine. To read my article click on the link here.

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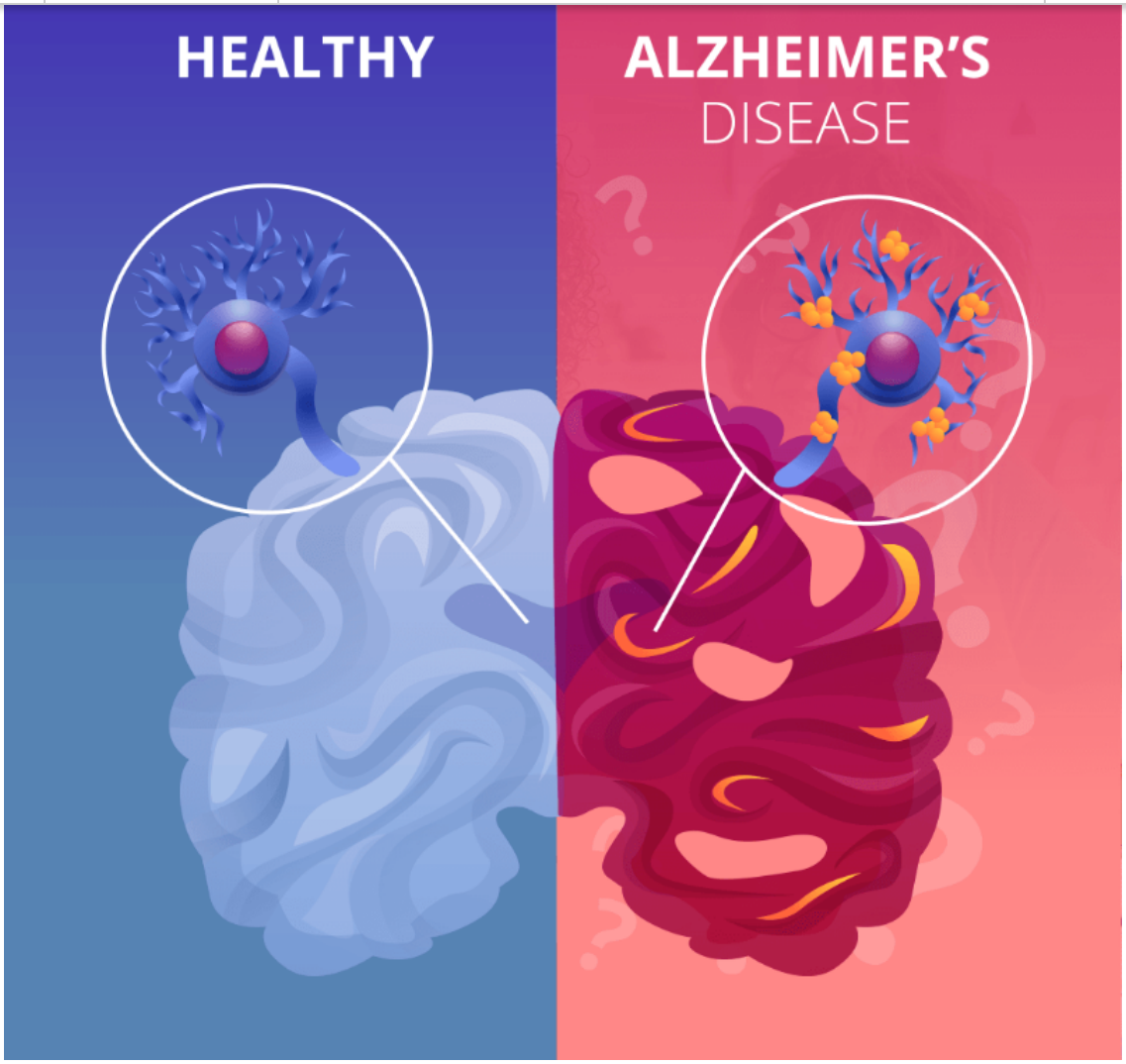


FDA Approves Alzheimer's Drug LEQEMBI®, Will Physicians Rush to Prescribe it?

Many pharma/biotech companies have been trying to develop a drug that halts the progress of Alzheimer's Disease (AD) for decades as this disease can affect anyone in the aging population and scientists are still trying to figure out the pathophysiology of this disease. There are two classes of drugs used to the symptoms of AD at different stages of the disease, cholinesterase inhibitors and Memantine.

Three cholinesterase inhibitors are commonly prescribed:

- **Donepezil (Aricept)** is approved to treat all stages of the disease. It's taken once a day as a pill.
- **Galantamine (Razadyne)** is approved to treat mild to moderate Alzheimer's. It's taken as a pill once a day or as an extended-release capsule twice a day.
- **Rivastigmine (Exelon)** is approved for mild to moderate Alzheimer's disease. It's taken as a pill. A skin patch is available that can also be used to treat severe Alzheimer's disease.

widely involved in brain functions — including learning and memory.

The first monoclonal antibody to be FDA approved for AD was Aduhelm® (Aducanumab) by Biogen on June 7, 2021, the first new treatment approved in nearly two decades since 2003.

Aduhelm® is a selectively binding amyloid aggregates in both the oligomeric and fibrillar states rather than amyloid monomers to remove amyloid plaque and the aim was to slow the progression of AD. It is administered as a monthly infusion that lasts one to three hours to administer. The cost of Aduhelm® was initially set at $56,000 per year before Biogen cut the price in half, to $28,000 annually. For Medicare to pay for the drug, patients have to be enrolled in a clinical trial, which limited coverage.

There was a lot of discussion about Aduhelm® regarding whether the drug slowed the progression and the side effect profile, headache, fall, diarrhea, and confusion/delirium/altered mental status/disorientation which are all signs of dementia and AD. There was a black box warning regarding amyloid-related imaging abnormalities (ARIA), highlights the risk of "serious and life-threatening events," including brain bleeding but which most commonly presents as temporary swelling in areas of the brain that usually resolves over time and does not cause symptoms, though some people may have symptoms such as headache, confusion, dizziness, vision changes, or nausea. A number of healthcare institutions such as Duke Health decided it will not provide aducanumab for the treatment of Alzheimer's disease at this time.

On January 6, 2023, Esai Co received an accelerated approval pathway from the FDA based on evidence that the drug removed amyloid from the brain. Researchers analyzed Leqembi's efficacy in a double-blind, placebo-controlled, parallel-group, dose-finding study of 856 patients with Alzheimer's disease. Patients receiving the treatment had significant dose- and time-dependent reduction of amyloid beta plaque, with patients receiving the approved dose of lecanemab, 10 milligram/kilogram every two weeks, having a statistically significant reduction in brain amyloid plaque from baseline to Week 79 compared to the placebo arm, which had no reduction of amyloid beta plaque.

On July 6, 2023, The FDA granted traditional approval on a second monoclonal antibody LEQEMBI® (lecanemab-irmb) by Esai and Biogen, the first and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline in adults with AD.

LEQEMBI® is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril*) and insoluble forms of amyloid beta (Aβ). Critically, LEQEMBI targets and clears the most neurotoxic form of Aβ that continuously

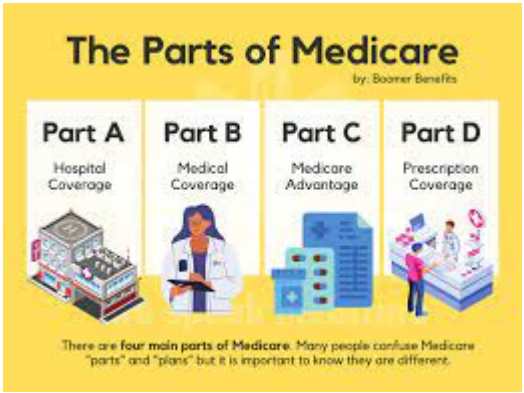
LEQEMBI® received unanimous backing by a panel of outside experts to the U.S. Food and Drug Administration who said the company's late-stage trial verified the drug's benefit for patients with early-stage disease. That study showed the drug slowed cognitive decline by 27% in early Alzheimer's patients, but was also associated with some serious side effects, the black box warning regarding amyloid-related imaging abnormalities (ARIA), including brain swelling and bleeding or microhemorrhages. But ARIA most commonly presents as temporary swelling in areas of the brain that usually resolves over time and does not cause symptoms.

LEQEMBI® will cost $26,500 a year which is below the current price set for Aduhelm at $28,000 a year. But LEQEMBI®'s price is still higher than what is recommended by the Institute for Clinical and Economic Review, a Boston-based research group that helps determine fair prices for drugs. Dr. David Rind, the institute's chief medical officer, said an appropriate cost for the drug is $8,500 to $20,600 a year.

In addition, another hurdle to jump over in order for LEQEMBI® to be reimbursed by Medicare, a government health plan for Americans 65 and older, it would require physicians to take part in a patient registry run by the Centers for Medicare and Medicaid Services (CMS).

Doctors will be required to submit demographic information on the provider and patient, the patient's diagnosis, and whether the patient is taking any drugs to treat or prevent blood clots, which may increase the risk of bleeding in the brain associated with the treatment.

CMS also wants to collect data on side effects such as brain swelling or hemorrhages, information on cognitive tests used to assess the patient and any prior treatment and require doctors to submit results of brain scans, spinal fluid tests or other measures used to assess levels of amyloid - an Alzheimer's protein that is the target of LEQEMBI® and other anti-amyloid drug.



Medicare will cover 80% of LEQEMBI®'s $26,500 cost or $21,200 per year.

disease progression and to slow cognitive and functional decline in adults with AD. Eventually Aduhelm® will be discontinued due to low sales revenue.

Whether physicians will be prescribe it immediately will vary from physician to physician depending on his/her risk tolerance or weighing the benefits against the risk and how much private insurance will reimbursement for the drug in covering the 20% not covered by Medicare.

The drug slowed cognitive decline by 27% in early Alzheimer's patients, but was also associated with a serious side effects, a black box warning regarding amyloid-related imaging abnormalities (ARIA), including brain swelling and bleeding or microhemorrhages. However, other side effects such as confusion/delirium/altered mental status/disorientation which are similar to signs of dementia and AD, how will physicians or care givers determine whether the drug is working?

Reimbursement will not be easy as Prior Authorization will be required and if approved all the requirements for the patient registry will make it cumbersome for the physician.

For the patient, even if LEQEMBI® is covered, Medicare normally only covers 80% of the drug unless the patient has supplemental insurance to cover the other 20% or it's $5,300 out-of-pocket/year after a patient meets their Medicare drug deductable and may pay premiums if they have Part D. Depending on the provider, the healthcare company providing the service on behalf of Medicare, now have a 5 tier payment fee: 1) preferred generic; 2) non-preferred generic; 3) preferred name brand; 4) non-preferred name brand 5) specialty drugs. Each provider of the plan has their own list for the 5 levels. And if it is not approved, one pays for the whole retail cost of the medication which can be quite expensive.

If the patient has Medicare Advantage (Part A, B, D), called Part C, depending on which plan s/he chooses, there may be monthly premium, a drug deductible before Medicare covers the cost and not all Medicare Advantage has drug coverage. Medicare insurance can get very complicated and one has to be careful because there are a lot of plans to choose from and whatever plan s/he chooses needs to meet what they need and want.

Closing Thoughts

The cost of healthcare insurance is more expensive for those on Medicare than a younger person who is usually healthier and has employers providing health insurance, because older patients, have more co-morbidities which require more testing, care and are usually on a lot of medications.

Health Insurance is like Life insurance where actuaries will calculate the probability that a person will die and charge premiums based on risk of dying and whether they have pay out and how much. The higher the risk, the higher the premiums. Health Insurance knows they have to pay more because of more co-morbidity and requiring more services, so older patient's cost more.

But this doesn't make sense because when one is working, they can afford health insurance. But when one is retired, they are on a fixed income which is not a lot and can't afford insurance unless they are independently wealthy. Something is wrong with this picture.

This same picture applies to vacation days. When one is young, one doesn't have many vacation days to do all the things they want to do both mentally and physically. But as one has been working for a long time and accumulates a lot of vacation days, they are too busy to take the vacation days or may not be able to take vacation to some of things they wanted to do when they were younger because they are not able to. Something is wrong with this picture.

In all three cases, it should be the opposite. But for many reasons not mentioned in this closing thoughts, it could be another newsletter. Food for thought.

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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.
