BioLines Weekender

To Our New Jersey Life Sciences Community:
Welcome to another edition of the Weekender.

It’s been an important week at BioNJ...one of those where we just cannot contain our excitement! (Actually to be honest, they are all pretty much like that!!!) What has us particularly excited about this week though, is that FDA Commissioner Dr. Stephen Ostroff and Dr. Bill Hait, Global Head, R&D at Janssen, J&J will participate in a Fireside Chat at our CEO Summit on October 9. Click here for details.

Meanwhile we are grateful to our Immediate Past Chairman Dr. Francois Nader who penned an op-ed published by The Star-Ledger explaining why it is imperative to ensure that Congress supports a patent system which protects innovation...and Patients...and the position of the U.S. as the world’s leader in medical innovation. Click here to review.

BioNJ applauds the U.S. House of Representatives for passing the Safe and Accurate Food Labeling Act this week with a solidly bipartisan vote. See the story herein for additional detail. We believe this legislation represents a reasonable way to ensure that consumers have access to the information they want while avoiding the complications which would be created by a patchwork of different state level food labeling laws.

Meanwhile we were so pleased at the report that “the pharmaceutical sector in Central New Jersey is seeing renewed growth”... and the shuffling of big pharma has subsided and resulted in “entrepreneurial former employees who have sparked a wave of new start-ups.” The result is that this market was deemed one of the most improved real estate markets in the country for Q2 2015, up 100 percent, driven by the pharmaceutical and communications sectors. See below for the full story.

In other good news, it was reported this week that in 2014, 100 Indian firms invested over $15 billion across all 50 states in the U.S. creating more than 91,000 jobs, according to a report by the audit and consultancy firm Confederation of Indian Industry and BioNJ Member Grant Thornton. New Jersey was second in job creation with 9,300 jobs. The jobs created are mainly in IT and telecom (40%) with 14% in pharmaceuticals and healthcare. See below for the full story.

Because Patients Can’t Wait,
The BioNJ Team

Click here to forward this issue of the Biolines Weekender to your colleagues.

Please send us your press releases at BioNJ@BioNJ.org to be included in the Weekender.

Do you know someone who wants to receive BioNJ information? Have them email BioNJ@BioNJ.org to be put on our mailing list.

BioNJ Calendar

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<th>BioNJ/LES Summer Bar-B-Que</th>
<th>Regulation A+ Webinar</th>
<th>BioHUB</th>
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<tr>
<td>Basking Ridge Country Club</td>
<td>10:00 a.m. - 11:00 a.m.</td>
<td>5:30 p.m. - 8:30 p.m.</td>
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<td>Register here for this event.</td>
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3rd Annual CEO Summit
October 8-9, 2015
Bridgewater Marriott
Registration coming soon!

Inspiring Women in S.T.E.M.
December 4, 2015
Sanofi, Bridgewater, NJ
Registration coming soon!

Putting Patients First: The Value of Medical Innovation
Brought to You by Celgene Corporation

What is the Value of Treatment for Individual Cancer Patients?

My last blog on the costs of drugs for the treatment of myeloma raised a number of issues for discussion, none more so than the heartfelt comment by Robert Fowler, who communicated to us his concerns about costs and the impact those costs may have on insurance for his fellow employees. Questions were also raised about the applicability of the “Value Framework” proposed by the American Society of Clinical Oncology (ASCO) to the assessment of myeloma. Can myeloma be evaluated in the same way as, let’s say, pancreatic cancer or other types of cancer? And what about the model proposed by Dr. Peter Bach at Memorial Sloan Kettering Cancer Center (MSKCC)? Is it reasonable to apply such models in a relatively simplistic and broad fashion?

Please click here for the full article.

Biotech Legend Lee Hood Gambles $36M on a Plan to Revolutionize Healthcare

Sequencing pioneer Lee Hood has already started enough biotechs to create his own cluster. And now he’s taking another shot at the founding scientist’s role, joining hands with a pair of high-profile biotech investment groups which are contributing a $36 million B round for a startup that has its sights set on nothing less than transforming healthcare — and our attitudes toward it.

Please click here for the full article.

NJ Industry News

Novo Nordisk Receives FDA Approval for FlexPro® PenMate® for People with Growth Hormone-Related Disorders

Plainsboro-based BioNJ Member Novo Nordisk announced the U.S. Food and Drug Administration (FDA) approval of FlexPro® PenMate®, designed for users of Norditropin® FlexPro® 5 mg, 10 mg, and 15 mg pens who dislike needles and prefer them to be hidden during the injection process.

Please click here for the full press release.

Second-Generation Investigational HIV-1 Maturation Inhibitor Demonstrates Positive New Phase IIa Results, Supporting Continued Development

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced additional Phase IIa proof-of-concept data for BMS-955176, a novel investigational agent designed to prevent the maturation of HIV-1. The study findings, which are being presented in a late-breaking oral presentation at the 8th IAS Conference on HIV Pathogenesis, Treatment and Prevention in Vancouver, confirmed the antiretroviral activity of BMS-955176 when administered with atazanavir (± ritonavir) and support further development of the second-generation HIV-1 maturation inhibitor.

Please click here for the full press release.

Integra LifeSciences Completes Acquisition of TEI Biosciences and TEI Medical

Plainsboro-based Integra LifeSciences Holdings Corporation announced that it has completed the acquisition of all of the outstanding shares of TEI Biosciences Inc. and TEI Medical Inc. ("TEI").

Please click here for the full press release.

Advaxis Expands Intellectual Property for Lm Technology(™) Platform in HER2

Princeton-based Advaxis, Inc., a clinical-stage biotechnology company developing cancer immunotherapies, announced that the United States Patent and Trademark Office (USPTO) has
Please states at the approved dose of 2 mg/kg every three weeks. Today’s approval allows marketing of KEYTRUDA in all 28 EU member states, based on a superior survival benefit as a monotherapy compared to ipilimumab, the current standard of care. The European Commission approval of KEYTRUDA is based on data from a Phase 3 clinical trial in which it was shown to be the first and only anti-PD-1 therapy to demonstrate overall survival benefit as a monotherapy in previously treated advanced squamous non-small cell lung cancer (SQ NSCLC). This approval allows for the marketing of nivolumab in all 28 Member States of the EU.

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to the investigational compound BMS-663068 when used in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in heavily treatment-experienced adult patients. BMS-663068 is an oral prodrug of the molecule BMS-626529 and first-in-class HIV-1 attachment inhibitor. The attachment inhibitor is designed to work differently than entry inhibitors, a current class of drugs that targets co-receptors’ activity or fusion after HIV attaches to the CD4+ host cell. BMS-663068 is thought to work at an earlier point in the replication process to prevent the virus’ initial interaction with immune cells entirely, and thus blocks its entry into the cell.

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced that the European Commission has approved KEYTRUDA® (pembrolizumab), the first major treatment advance in squamous NSCLC in more than a decade in the European Union (EU). Nivolumab is also the first and only PD-1 immune checkpoint inhibitor to demonstrate overall survival (OS) in previously-treated metastatic SQ NSCLC. This approval allows for the marketing of nivolumab in all 28 Member States of the EU.

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced that the European Medicines Agency (EMA) has validated two of the company’s type II variation applications, which seek to extend the current indication for its Immuno-Oncology agent, Opdivo. Validation of the applications confirms that the submissions are complete and starts the EMA’s centralized review process.

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced that the European Commission has approved KEYTRUDA® (pembrolizumab), for Both First-line and Previously-treated Patients with Advanced Melanoma. KEYTRUDA received European Commission regulatory approval based on Phase 3 data which showed it is the first and only anti-PD-1 therapy to provide a statistically superior survival benefit as a monotherapy compared to ipilimumab, the current standard of care for advanced melanoma. Today’s approval allows marketing of KEYTRUDA in all 28 EU member states at the approved dose of 2 mg/kg every three weeks.

Agile Therapeutics Announces Allowance of Several Patents on Novel Dosing Regimens for Its Pipeline of Follow-On Contraceptive Products

Princeton-based BioNJ Member Agile Therapeutics, Inc., a women’s health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, announced that the U.S. Patent and Trademark Office issued Notices of Allowance between July 21 and 23 for four patent applications with claims directed to novel transdermal contraceptive dosing regimens.

Please click here for the full press release.

Bristol-Myers Squibb Receives U.S. FDA Breakthrough Therapy Designation for Investigational HIV-1 Attachment Inhibitor for Heavily Treatment-Experience Patients

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to the investigational compound BMS-663068 when used in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in heavily treatment-experienced adult patients. BMS-663068 is an oral prodrug of the molecule BMS-626529 and first-in-class HIV-1 attachment inhibitor. The attachment inhibitor is designed to work differently than entry inhibitors, a current class of drugs that targets co-receptors’ activity or fusion after HIV attaches to the CD4+ host cell. BMS-663068 is thought to work at an earlier point in the replication process to prevent the virus’ initial interaction with immune cells entirely, and thus blocks its entry into the cell.

Please click here for the full press release.

European Commission Approves Nivolumab BMS, the First PD-1 Immune Checkpoint Inhibitor in Europe Proven to Extend Survival for Patients with Previously-Treated Advanced Squamous Non-Small Cell Lung Cancer

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced that the European Commission has approved Nivolumab BMS for the treatment of locally advanced or metastatic squamous (SQ) non-small cell lung cancer (NSCLC) after prior chemotherapy. This approval marks the first major treatment advance in SQ NSCLC in more than a decade in the European Union (EU). Nivolumab is also the first and only PD-1 immune checkpoint inhibitor to demonstrate overall survival (OS) in previously-treated metastatic SQ NSCLC. This approval allows for the marketing of nivolumab in all 28 Member States of the EU.

Please click here for the full press release.

European Medicines Agency Validates Two Parallel Type II Variation Applications to Extend the Opdivo (nivolumab) Indication in Europe

Princeton-based BioNJ Member Bristol-Myers Squibb Company announced that the European Medicines Agency (EMA) has validated two of the company’s type II variation applications, which seek to extend the current indication for its Immuno-Oncology agent, Opdivo. Validation of the applications confirms that the submissions are complete and starts the EMA’s centralized review process.

Please click here for the full press release.

European Commission Approves Merck’s Anti-PD-1 Therapy, KEYTRUDA® (pembrolizumab), for Both First-line and Previously-treated Patients with Advanced Melanoma

Kenilworth-based BioNJ Member Merck, known as MSD outside the United States and Canada, announced that the European Commission has approved KEYTRUDA® (pembrolizumab), the company’s anti-PD-1 therapy, for the treatment of advanced (unresectable or metastatic) melanoma in adults. The European Commission approval of KEYTRUDA is based on data from three clinical studies conducted in more than 1,500 first-line and previously-treated patients with advanced melanoma. KEYTRUDA received European Commission regulatory approval based on Phase 3 data which showed it is the first and only anti-PD-1 therapy to provide a statistically superior survival benefit as a monotherapy compared to ipilimumab, the current standard of care for advanced melanoma. Today’s approval allows marketing of KEYTRUDA in all 28 EU member states at the approved dose of 2 mg/kg every three weeks.

Please click here for the full press release.
Merck Announces European Medicines Agency Acceptance of Marketing Authorization Application for Grazoprevir/Elbasvir, an Investigational Therapy for Treatment of Chronic Hepatitis C Infection

Kenilworth-based BioNJ Member Merck, known as MSD outside the United States and Canada, announced the European Medicines Agency (EMA) has accepted for review a marketing authorization application (MAA) for grazoprevir/elbasvir (100mg/50mg), an investigational, once-daily, single-tablet combination therapy for the treatment of adult patients with chronic hepatitis C (HCV) genotypes (GT) 1, 3, 4 or 6 infection.1 The EMA will initiate review of the MAA under accelerated assessment timelines.

Please click here for the full press release.

Merck Marks 30-Year Milestone in Commitment to Innovation and Care in HIV/AIDS

Kenilworth-based BioNJ Member Merck, known as MSD outside the United States and Canada, announced that the company's commitment to HIV and AIDS, which started with a research and development program initiated in the mid-1980s during the early years of the epidemic, is now entering its fourth decade. To commemorate Merck's 30 years of commitment in this area, the company is launching a new effort, "Positively Committed." The campaign highlights the company's contributions, including the development of innovative therapies to address the unmet medical needs of people infected with HIV-1.

Please click here for the full press release.

New Study Shows Florbetapir F 18 Injection Scans Led to Change in Diagnosis and Management of Patients Being Evaluated for Cognitive Decline

Bridgewater-based BioNJ Member Eli Lilly and Company and Avid Radiopharmaceuticals, Inc., a wholly owned subsidiary of Lilly, announced new data showing that knowledge of amyloid status as determined by Florbetapir F 18 Injection imaging altered diagnosis and management in the majority of patients being studied. This is the first study to look at the impact of amyloid imaging on diagnosis and actual patient management using a randomized, controlled prospective design. These findings were presented at the Alzheimer's Association International Conference® 2015 in Washington, D.C.

Please click here for the full press release.

Lupin Acquires GAVIS to Expand US Generic Business

Pharma Major Lupin Limited (Lupin) has entered into a definitive agreement to acquire privately held GAVIS Pharmaceuticals LLC and Novel Laboratories Inc. (GAVIS), subject to certain closing conditions, in a transaction valued at USD 880 million, cash free and debt free. The transaction has been unanimously approved by the Boards of Directors of Lupin and GAVIS. The acquisition enhances Lupin's scale in the US generic market and also broadens Lupin's pipeline in dermatology, controlled substance products and other high-value and niche generics. GAVIS brings to Lupin a highly skilled US based R & D organization which would complement Lupin's Coral Springs, Florida, inhalation R&D center. GAVIS's New Jersey based manufacturing facility will become Lupin's first manufacturing site in the US.

Please click here for the full press release.

Hackensack Edges Morristown for State's Top Hospital in Prestigious U.S. News Rankings

BioNJ Member Hackensack University Medical Center was once again named the top hospital in New Jersey by the prestigious U.S. News & World Report Best Hospitals rankings.

Please click here for the full article.

Big Names Welcome $50M Newark Venture Fund

Business leaders and public officials gathered Monday to launch Newark Venture Partners, a $50 million early-stage technology venture fund supported by some of the city's top corporate leaders.

Please click here for the full press release.

Valeant Pharmaceuticals Agrees to Acquire Amoun Pharmaceutical

Bridgewater-based Valeant Pharmaceuticals International, Inc. announced that it has entered into a definitive agreement under which Valeant will acquire Mercury (Cayman) Holdings, the holding company of Amoun Pharmaceutical, for consideration of approximately U.S. $800 million, plus contingent payments.

Please click here for the full press release.
NJ Ecosystem News

NJ Office Market’s Momentum Continued in Q2

The U.S. office market continued its healthy pace in the second quarter of 2015, according to commercial real estate services firm Cushman & Wakefield.

The most improved markets were Northern Virginia, up 138 percent, with activity driven by government-related tenants and private sector tenants that have once again become active; and Central New Jersey, up 100 percent, driven by the pharmaceutical and communications sectors.

Please click here for the full press release.

Indian Firms are Pouring Billions into U.S. States

In 2014, 100 Indian firms invested over $15 billion across all 50 states in the U.S. creating more than 91,000 jobs, according to a report by the audit and consultancy firm Confederation of Indian Industry and Grant Thornton. The states where the most job were created were New Jersey with 9,300 jobs, California with 8,400 and Texas with 6,200. The jobs created are mainly in IT and telecom (40%) but also in pharmaceuticals and healthcare (14%), mining and manufacturing (14%), and financial services (6%).

Please click here for the full press release.

People in the News

Drs. Schaber and Straube Discuss Treatment of Cutaneous T-Cell Lymphoma in Recent Publication

Drs. Christopher Schaber and Richard Straubem are working to change the prognosis for patients with rare and poorly treated diseases. They introduce Princeton-based BioNJ Member Soligenix and its investigational drug, SGX301 (synthetic hypericin), for the treatment of cutaneous T-cell lymphoma.

Please click here for the full article.

NJBIZ Announces CFO of the Year Finalists

NJBIZ is pleased to announce the finalists for its 2015 CFO of the Year awards. The CFO of the Year awards celebrate New Jersey's financial executives at all levels - including chief financial officers, controllers, chief accounting officers and more - who contribute to the economic growth of both their company and the Garden State. Congratulations to Shane Kovacs of BioNJ Member PTC Therapeutics and Edward Sitar of BioNJ Member Cancer Genetics Inc. for being chosen as finalists.

Please click here for the full press release.

Government Affairs News

The Safe and Accurate Food Labeling Act Passes U.S. House With Bipartisan Vote

In a victory for consumer choice, science and fact-based food labeling, the Coalition for Safe Affordable Food applauded the U.S. House of Representatives for passing the Safe and Accurate Food Labeling Act today with a solidly bipartisan vote. Today's vote is a testament to the reasonable approach this legislation takes to ensure consumers have access to the information they want while avoiding the costly price hikes and misinformation associated with a patchwork of food labeling laws.

Please click here for the full press release.

Hedge Funds, 'Reverse Trolls’ Crushing Biopharma Innovation

In an attempt to increase efficiency and protect innovation, Congress passed the 2012 America Invents Act (AIA). It established “inter partes review” (IPR), a quick and easy way to get rid of nuisance patents. The results have been quite impressive with more than three-quarters of the patent claims challenged via IPR being invalidated upon further review. But, while the system has been very popular and effective for technology companies, two unintended consequences of the IPR law have given rise to practices that very much hurt biopharmaceutical innovation - "reverse trolls" and stock manipulation. You see, those acting in bad faith also have a legal right to file such challenges, and they do.

Please click here for the full article.
Entrepreneurship Resources

Highly-Educated Workforce Helps Attract Scientist-Turned-Entrepreneur Navneet Puri to Grow Multi-Million Dollar Company in New Jersey

The New Jersey Economic Development Authority (EDA) continues its series highlighting how entrepreneurs and investors are helping to build New Jersey's technology ecosystem.

Please [click here](#) for the full press release.

University/Institution News

Rutgers Cancer Institute of New Jersey Examines Two to Three Day Radiation Course for Breast Cancer

New Brunswick-based BioNJ Member Rutgers Cancer Institute of New Jersey is leading a clinical trial examining if a certain dose of radiation given over a short period of time to the part of the breast affected by cancer is beneficial. The trial, known as the TRI-faction Radiotherapy Utilized to Minimize Patient Hospital Trips -- or TRIUMPH-T Trial -- will explore the effect of treating patients with radiation delivered over a shortened period of two to three days versus longer periods associated with traditional radiation therapy. A previous study by Cancer Institute of New Jersey researchers showed the approach of giving radiation therapy over a two day period is safe.

Please [click here](#) for the full article.

Need Another Reason to Understand Why the Rutgers-UMDNJ Merger was So Big? Listen to the Dean of the Medical School

Dr. Robert Johnson had been associated with UMNDJ for much of his life. And he's the first to admit that when he heard the school was merging with Rutgers University, he didn't think it would make much of a difference -- other than changing a few signs, he joked.

Please [click here](#) for the full article.

Rowan Research Gives Hope to Patients of Canavan Disease Through Commercial Agreement With Bamboo Therapeutics, Inc.

Glassboro-based BioNJ Member Rowan University and Bamboo Therapeutics, Inc. have entered into an asset transfer agreement to commercialize a novel gene therapy for the treatment of Canavan disease. A rare but devastating neurological disease that tragically takes a child's life by age 10, Canavan disease is one of the most common and complex degenerative cerebral diseases in infants.

Please [click here](#) for the full press release.

BioNJ Purchasing Consortium

BioNJ's Purchasing Consortium: Enhanced Member Benefits, Saving Money and Time, Helping You Help Patients

Through [BioNJ's Purchasing Consortium](#), our Members have access to programs and services negotiated by BioNJ and BIO and offered at favorable rates and terms to save your company money. Through our affiliation with BIO, BioNJ is part of the largest cost-savings program for the life science industry with the purchasing power of over 2,800 biotech companies. Our group discounts are for Members only and your Membership is the gateway to this purchasing power to save your company critical resources.

From lab supplies to insurance and office supplies to shipping, take a fresh look at your savings and the current suppliers in BioNJ's Purchasing Consortium, including Fisher Scientific, UPS, CSS Building Services, American Express Meetings and Events, Dynamic Strategies, Business Wire, Chubb Group of Insurance Companies, Clean Harbors, Femto Scientific, Humboldt Moving, Informa, Linde, Office Depot and Tech Depot.

For more information on how you can sign up for these Member discounts and save your working capital, contact Linda Pontell, Director of Marketing, Member Services at LPontell@BioNJ.org.

BioNJ Talent Services
**Job Leads**

Please [click here](#) to see the list of available position listings from companies such as Merck, Celgene, Covance, Nova Nordisk and Actavis.

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**BioNJ Tweets of the Week**

[Image of Twitter bird with text: Click Here for BioNJ's Tweets of the Week!]

Please contact BioNJ at [BioNJ@BioNJ.org](mailto:BioNJ@BioNJ.org) or 609-890-3185 with any questions.

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