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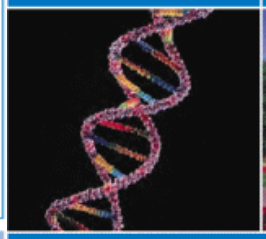

NEWSLETTER

March 2016, Volume XXVI, No. 2

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President's Message: The Local Biopharma Sector is Booming & ISPE is Ready!

My Fellow Members,

As you will notice, ISPE has a new logo. The new logo is designed to convey strong, positive messages about who we are and what we offer. A modern adaptation of the original ISPE globe reflects our continuous efforts, since 1980, to lead scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. It has been specially designed to symbolize not only our name, but also what we stand for.

As pharmaceutical engineers, our core membership consists of those who work in and serve the manufacturing operations of pharma companies. Here in the Boston Area Chapter, it can further be defined as those in the biopharma manufacturing sector. And how that sector is booming here in New England! Every one of the leading bio manufacturers in the region has major capital projects planned or underway. The list is a veritable who's who of the industry: BMS, Pfizer, Shire, Lonza, Novo Nordisk, Regeneron, Biogen, Amgen, Novartis, Sanofi Genzyme - all have major projects underway.

And this month, Boston-area biotech Alnylam closed on its deal to buy a 12-acre site in Norton, Massachusetts where they will build a new greenfield plant to manufacture their pipeline of products. The total investment in the site is expected to be between $100 and $200 million. Alnylam could have built the plant anywhere in the world but is committed to growing in Massachusetts. Christine Lindenboom, Alnylam's Vice President of Investor Relations and Communications, couldn't have said it any better: "We were founded in Massachusetts. Our headquarters is in Cambridge. This is another important commitment to our presence in Massachusetts."

This new project, as well as all the others, reflects the industry's recognition that this region is where they need to be to take advantage of the synergies that are generated by the critical mass of operating companies, research universities, teaching hospitals, financial capital, and local government that is business friendly, especially to those companies in the life sciences. Our role to deliver technical and operational solutions to support ISPE Members across the industry is a key component in ensuring that these companies are able to continue to find professionals with the expert knowledge they need to create high-quality, cost effective GMP solutions.

From our flagship event, the ISPE Product Show, to our monthly educational programs, the Chapter is committed to partnering with the industry to deliver the training needed to ensure that our region remains the Hub of Life Sciences. We will be rolling out some new initiatives soon in this area to help the next generation of pharma engineers prepare for the challenges of all these projects. And the spring is chock full of educational and social events as you will see within this newsletter - I hope to see you soon at one (or more) of them!

Warm Regards,

H. Steven Kennedy

Chapter Bulletin Board

Chapter Launches New Mentoring Program

The Chapter is pleased to announce our brand new Mentoring Program, which was officially launched at the Product Show. If you think you could benefit from the experiences of others or if you think you can share your experiences to help a fellow Member, then this is the place for

you. Mentoring is a positive experience as well as a growth opportunity for both the mentor and mentee. Check out the new "Mentoring Program" tab on the Chapter website to learn more http://www.ispeboston.org/mentoringdescription.html. All you have to do is register and the Chapter will pair you up.

The mentoring program took almost a year to build and was a truly multidisciplinary commitment involving major efforts from Samir Gondalia (Membership Committee Chair), Chris Ciampa (YP Committee Chair) and Brian Hagopian (Student Development Committee Co-Chair), all of whom should be recognized for their contributions to developing and launching the program.

eNewsletter Ad Space Expanding - Sign Up Now!

Now that the Boston Area Chapter has grown to include over 1750 members located throughout all of New England, our eNewsletter ad space is also increasing. This gives Chapter Members a new opportunity to join the ranks of eNewsletter advertisers and gain valuable media exposure while helping to support the Chapter's expanding activities.

This additional ad space will disappear quickly so don't waste any time. Choose the option that works best for you - ads are available in two sizes and run for six months or a full year - then contact the Chapter office at (781) 647-4773 or office@ispeboston.org.

Support Your Chapter - Become a Sponsor!

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource containing all the information you need to know to become a Chapter Sponsor.

We invite you to visit the sponsorship page at http://www.ispeboston.org/become_a_sponsor.html to explore the full range of sponsorship options available. Using the sponsorship application as your worksheet, you can view your savings as you select various combinations of sponsorship options - the more you choose, the bigger your discount!

So don't delay, visit http://www.ispeboston.org/become_a_sponsor.html and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members. Or, if you'd rather, contact the Chapter office at (781) 647-4773 or office@ISPEBoston.org and we'll be happy to help!

Upcoming Chapter Events - Mark Your Calendar

Thursday, March 24, 2016

ISPE Learning Through Doing: The Interplay of Pilot Plant, Product, and Process

Shire, Lexington, MA

EVENT SUMMARY

The Pilot Plant plays an instrumental role both in material supply for preclinical and clinical development purposes as well as scale-up of technology and operations. The ultimate goal is developing a solid process that can be successfully transferred to a commercial manufacturing site. In the developing age of customizable, specialized biotechnology therapies, how will Pilot Plants adapt to new technology and what niche will the Pilot Plant play in the future product development lifecycle?

This educational event will include a presentation and panel discussion of Pilot Plant leaders from notable local biotechnology companies. The current and future role of the pilot plant in the product development lifecycle will be examined. The group will first present and comment on benchmarking data collected across their companies. The group will then discuss agility and adaptability of their pilot plants in regards to the current and future pipeline and technologies.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=576

Thursday, March 31, 2016

RE-SHOWING: ISPE Learning Through Doing: The Interplay of Pilot Plant, Product, and Process

Tech Collective, Providence, RI

WPI Biomanufacturing Education and Training Center at Gateway Park, Worcester, MA

Redhook Ale Brewery - Alemaker's Hall, Portsmouth, NH

PROGRAM SUMMARY

Join us at the WPI BETC at Gateway Park in Worcester, MA or Tech Collective in Providence, RI or the Redhook Ale Brewery in Portsmouth, NH for a re-showing of the program recorded at Shire, March 24,

Previous Issues

2016. A networking reception, including refreshments and appetizers, will be hosted before the presentation at each location.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=634

Thursday, April 7, 2016

ISPE Young Professionals: Pizza, Networking, and Bowling

The Flatbread Company, Somerville, MA

EVENT SUMMARY

Back by Popular Demand! Come join the Young Professional's at The Flatbread Company in Davis Square for an evening of pizza, beer, socializing, and candlepin bowling at the famous Sacco's Bowl Haven! Enjoy a variety of wood-fired, clay oven flatbread pizzas (vegetarian options will be offered), salad, and dessert. Bowling shoes will be provided and a cash bar will be available.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=645

Wednesday, April 13, 2016

ISPE Bruins Game and Networking at Providence

Providence Bruins at Dunkin Donuts Center, Providence, RI

EVENT SUMMARY

Join us at an evening filled with fun, excitement, food, drinks and networking! Catch the Providence Bruins play the Springfield Falcons from an amazing location. The event includes access to the game, cash bar, as well as a buffet (including but not limited to chicken tenders, buffalo wings, hot dogs and more!). It's an event worth attending because don't just watch, socialize and network while Bruins play!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=648

Wednesday, April 20, 2016

ISPE Annual Student Poster Contest 2016

WPI's Biomanufacturing Education and Training Center (BETC), Worcester, MA

EVENT SUMMARY

Want to Show Off Your Work and Win $500.00? Register to Compete in the ISPE Boston Area Chapter Annual Student Poster Contest! Two winning student posters, one each from the graduate and undergraduate categories will receive a $500 cash prize and a FREE TRIP to compete at the International Student Poster Competition at ISPE's Annual Meeting in Atlanta, GA. on September 18-21, 2016. Winners of the International competition receive cash awards and have the opportunity to publish their materials in ISPE's Pharmaceutical Engineering magazine, as well as other Chapter/Affiliate publications.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=642

Monday, May 9, 2016

ISPE Spring Golf Tournament

Ledgemont Country Club, Seekonk, MA

EVENT SUMMARY

Get ready for Spring Golf! Register today for golf, lunch and dinner with fellow colleagues. Many sponsorships are available!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=647

Sneak Preview of Upcoming Events

Thursday, April 20, 2016
ISPE Science, Technology, and Society
WPI Biomanufacturing Education and Training Center at Gateway Park, Worcester, MA

Thursday, May 19, 2016

ISPE Single Use
Shire, Lexington, MA

Newsletter Archive

Bringing in the New Year at Blazing Paddles

by Eva Price, New England Lab, with photos by Joyce Chiu, Shire

The Chapter's Social Committee hosted the 9th Annual New Year Social (previously known as the Holiday Social) on Thursday, January 14 at Blazing Paddles in Boston. With ping pong paddles in hand, over 70 Chapter Members and guests came together for a night of recreational competition and networking. Hosted in an engaging venue and brimming with a wide variety of appetizers, the night was destined for success!

Chapter President H. Steven Kennedy congratulates ping pong tournament winners (top to bottom) Daniel Kim (first), Prathiba Sampath (second) and Jesse McLaughlin (third).

The event centered around a high-energy ping pong tournament that was incentivized by Visa Gift Cards for the top three competitors. In between games, guests who wanted to see if they "still had it" could venture out to the batting cages at Fenway. Some also decided to test their skills in cornhole games throughout the night. There was no shortage of jokes and excitement with all of these activities! As the ping pong tournament neared its end, the whole group gathered to cheer on the final matches. Congratulations to Jesse McLaughlin, Prathiba Sampath, and Daniel Kim who rose to the top!

Last but certainly not least, a 50/50 raffle was held to benefit the ALS Association (http://www.alsa.org/). It is a great honor to support this wonderful charity devoted to fighting and ultimately curing Lou Gehrig's Disease as they lead the way in research, superior care for patients and their families, and public education. It was a great night that benefited a great cause!

The Social Committee would like to thank everyone who attended for helping to help make the entire evening at Blazing Paddles a smashing success! And a special thank you to the sponsors who made this possible: Albireo Energy (formerly GxP Automation), A/Z Corporation, Boston Analytical, DPS, Jensen Hughes, and TRIA. We hope to see everyone at the next New Year Social!

In the meantime, we are looking forward to our Annual Ski Trip at Waterville Valley on March 4, the Spring Golf Tournament at Ledgemont Country Club in Seekonk on May 9 and the Summer Golf Tournament at Lake Winnipesaukee Golf Club on August 8.

Members Learn "How to Build a Bio" in Lowell, Warwick and Worcester

by Mark Braatz, FW Webb; Peter Cramer, M+W Group; and Jeff Odum, IPS; with photos by Joyce Chiu, Shire

The January educational program,"How to Build a Bio," was presented by Peter Cramer and Jeff Odum, both well respected experts in the field of design, construction and commissioning of biotech facilities. Peter is the Vice President of Life Science Facility Design for the M+W Group with over 25 years in the process architectural field. Jeff is Director of Operations, Biotech Lead, for IPS. Both are accomplished

speakers and authors in their fields which made for a very educational evening.

Members enjoyed a networking reception and mini-tours of the Core Research Facilities prior to the presentations.

The event was held at the Mark and Elisa Saab Emerging Technologies and Innovation Center (Saab ETIC) at UMass Lowell (UML) and included "lightning" tours of its state of the art Core Research Facilities. The UML research staff did a great job showcasing their facility and presenting their "vision" for the future. The event attracted a great turnout with over 75 attendees including a number of students. The program used a "town hall" format that encouraged audience participation throughout. Following the networking reception and facility tours, Dr. Joseph Hartman, Dean of the Francis College of Engineering, opened the presentation with an overview of the program at UML, then turned the floor over to the speakers. Jeff and Peter immediately demonstrated why they are considered recognized experts in their fields, jumping into the topic at full speed.

Chapter Meeting Manager Mark Braatz (center) with UMass Lowell hosts Theresa Hamlin, Director of Core Research Facilities, and Joseph Hartman, Dean of the College of Engineering.

According to Jeff, today's biotech industry faces a number of challenges and opportunities that directly impact facility design approaches and decisions. The implementation of flexibility across the typical multi-phase product life cycle requires a keen understanding of product-process-facility synergy in order to create operational efficiency. Enabling technologies such as single-use platforms will expand opportunities for increased utilization while also introducing new operational risks that must be addressed. In addition, the advance of the science, producing higher titers and yields, creates opportunities for both repurposing of existing operations and hybrid manufacturing scenarios. The session addressed these and a number of options that are creating more flexible, highly efficient and highly utilized operating facilities for biomanufacturing today.

Presenters Peter Cramer and Jeffrey Odum impressed the audience with their understanding of the design, construction and commissioning of biotech facilities.

In Peter's view, the industry will continue to be challenged to deliver truly flexible biopharmaceutical manufacturing facilities with significant reductions in schedule, cost, and client operating resources. A flexible "platform" approach can provide advantages in achieving reductions in schedule, cost and internal resources, while at the same time delivering production flexibility where it really matters. Analysis tools can highlight the advantages and disadvantages of the different project delivery methods on production flexibility and provide a method to quickly gain insight into which platform approach is best suited to a specific project's needs.

During the discussion, various platform and project delivery approaches were presented to demonstrate how they can be evaluated against specific project requirements at the start of a project. The presenters also demonstrated how a decision tree can be used to guide the decision making process given real world project conditions and constraints.

This was only a small piece of the tremendous amount of knowledge shared with attendees, who were able to participate throughout the evening. For those not able to attend, the event was taped and rebroadcast at two sites a week later, the Crowne Plaza Hotel in Warwick, RI and WPI in Worcester. Peter Cramer was onsite in Warwick to do the Q&A session and we had record numbers attend the Warwick site. Based on the success of the re-shows at these locations, the Chapter plans to add a third site in Portsmouth for future events.

The Chapter would like to thank Peter Cramer and Jeff Odum for sharing their expertise with our membership; our hosts at all three locations; and the Educational Program Committee for organizing this very successful event.

Biogen Membership Drive Attracts New Chapter Members

by Ying Cai, Biogen, and Samir Gondalia, Pfizer

Not only is Biogen a leader in the local biotech industry, it's employees are also very active in ISPE with over 40 current Members participating in Chapter activities, serving on the Chapter's committees or volunteering to help organize Chapter activities. To further strengthen the ISPE presence at Biogen, the Chapter's Membership Committee organized a membership drive at the company's Kendall Square Building 1 on January 27. The purpose of this event was to introduce Biogen employees to the many benefits of ISPE membership and make them aware of the array of local activities planned by the Chapter for 2016.

Membership Committee Member Ying Cai (second from left) with fellow Biogen employees (l to right) Ryan Flansburg, KerriAnn MacNeill, David Dybes, Nicole DeCruz, and John Hickey.

Katherine Batten from the Chapter's administrative staff and Membership Committee member and Biogen engineer Ying Cai set up the ISPE booth just outside the cafeteria during the lunch hour when employees would have the time to stop and chat. They distributed recent issues of Pharmaceutical Engineering, ISPE membership benefit brochures and flyers describing upcoming Chapter activities. Employees who stopped by were excited to hear about the professional development and career advancement opportunities ISPE has to offer and a number of them provided their contact information and committed to becoming ISPE Members. The booth was also a magnet for current Members who were eager to sign up for upcoming networking events like the ski trip on March 4 and the bowling social on April 7.

ISPE and the local Chapter provide a platform for the New England pharmaceutical professionals who want to trade practical knowledge with their peers, keep current on the latest trends in the industry, brush up on the basics, advance their technical knowledge, or simply meet and mingle with industry professionals who speak their language. We do this by hosting networking and educational events, and career advancement workshops; through our professional publications; and by organizing the largest life sciences Product Show in New England.

If anyone would like to help the Chapter attract new Members by hosting a similar membership drive at their own company, please contact Membership Committee Chair Samir Gondalia at Samir.Gondalia@pfizer.com.

Cure the Winter Blues with the Chapter's Young Professionals

by Christopher Ciampa, Thermo Fisher Scientific

How time flies! We have completed the first months of 2016 relatively unscathed weather-wise with no major snowstorms thus far. And we YPs are doing our very best to help cure the winter blues with some hot events. Here's what the next few months have in store. All this and spring, too!

Chapter YPs leave the winter weather behind and lace up for an evening of indoor fun at Roller World.

Planning for the March "roundtable" educational program is well underway. This will be the first roundtable session hosted by the YP group in the history of the Chapter! The timing couldn't be better since the roundtable will be perfect for graduating students who will soon be entering the industry, as well as YPs who are relatively new to the industry. The current plan is to piggyback on the educational program at Shire in Lexington on Thursday, March 24. The program will discuss the role of the pilot plant in the product lifecycle and will be preceded by tours of Shire's pilot plant facility. While the tours are taking place, the YPs will enjoy an informal roundtable with the panelists from Shire, Amgen, AbbVie, Pfizer and Biogen. Following the roundtable, YPs will rejoin the rest of the attendees for the educational program. What a great introduction to the pilot plant for students and YPs new to the industry!

We have two social events coming up in April for you to look forward to. Due to the success of the bowling social last year, the YPs will be heading back to Sacco's Bowl Haven in Davis Square, Somerville on Thursday, April 7 for flatbread pizza and candlepin bowling. The format will be the same as last year: one hour for dinner/networking (pizza, salad and dessert, with beer on tap available for purchase) and two hours for candlepin bowling. If last year is any indication, you'll have a blast so be sure to be there!

The second social event is going to be something new. Now that the Chapter has merged with the New England Chapter, we want to host an event outside of the Boston area. Providence is home to many members of the former New England Chapter so we are trying a Rhode Island YP event on Wednesday, April 13. The plan is to attend a Providence Bruins game. (The Providence Bruins belong to the American Hockey League.) We are still in the planning stages at this time, so keep an eye out for more details about this event in the next month or so.

Also in April, we will be hosting our annual dual track educational program, this time at WPI. The overall topic will be "Science and Technology: What Will the Next Ten Years Bring?" with the YP/student track covering "The Effect Regulatory Changes Will Have on Drug Development." In addition, the Chapter's Annual Student Poster Contest will be judged the same evening - with the posters on display during the networking reception - so plan to be there to show your support for the student participants! We are also looking to partner with WPI in the fall when they are holding a week-long seminar on bioreactors. We may do an evening event in conjunction with the seminar so students and YPs can see the bioreactors.

As a final note, looking towards the end of 2016, we are in the pre-planning stages for a second dual track educational program to be held in November. The YP portion will be "Regulatory 101: Jargon for Engineers" and will be hosted in the Boston area, preferably at one of the local colleges.

As always, we want to hear from you! If you have any suggestions, or would like to attend one of the regularly scheduled YPC meetings, please don't hesitate to reach out to me (christopher.ciampa@gmail.com).

The Chapter's Student Members Warm Up with Lots of Spring Activities

by Brian Hagopian, Clear Water Consulting, and Paige Kane, Pfizer, with photo by Andre Walker

We've got a busy spring coming up for our students with lots of activities underway or in the planning stages:

- Fourth Annual Career Workshop held on January 30
- Mentoring program gaining traction
- Jobs posted for internships, co-op's and full time positions
- Shire "roundtable" and plant tour - both in March
- Outreach to Career Fairs on several campuses in February, March and April
- Student Poster Contest on April 20 at WPI
- Scholarship Applications due by June 1

Northeastern's spacious Raytheon Amphitheater hosted the Chapter's fourth annual Career Workshop on Saturday, January 30. Students came from far and wide to learn from the experts at this all-day event which featured industry pros helping students with cover letters, resume building, making winning first impressions, managing their digital footprint, interviewing skills, building their networks and much more. Thanks to Dave Novak, Andre Walker, Chris Opolski, Paige Kane and Laura Poisson for their time and

effort and to Jillian Willard, Chris Ciampa, Brody Stara and Sylvia Beaulieu for sharing their career stories with those in attendance.

Past President Sylvia Beaulieu (shown) and Chapter Members Jillian Willard, Chris Ciampa and Brody Stara, shared lessons learned and tips for career success with attendees.

The Chapter's mentoring program is brand new, so take advantage of this opportunity to find someone whose experience can help you as you chart the next steps in your education and career. Open to ISPE members of any age or experience level.

With the spring semester in full swing, the Chapter is actively helping students find employment, whether it's a summer internship, co-op, or a full time position. The Chapter offers local life science companies a free job posting service to help them fill vacancies. Check out the "Jobs and Internships" section of the Chapter website and "like" the Chapter's Facebook page to receive notifications when positions are posted. Our goal is to have at least 75 positions posted between now and the summer and we're well on our way! Remember, you have to be an ISPE member to access these positions.

The Student Development Committee and the Young Professionals are each planning special events at Shire in March. The first is the YP "roundtable" that will accompany the Chapter's educational program on Thursday, March 24. This event is a perfect fit for students, especially graduating seniors preparing to enter the workforce. The evening's program will discuss the role of the pilot plant in the product lifecycle and will be preceded by tours of Shire's pilot plant facility. While the tours are taking place, YPs and students will participate in an informal roundtable discussion with the panelists from Shire, Amgen, AbbVie, Pfizer and Biogen. What a great introduction to the pilot plant for students and YPs new to the industry!

The student specific tour of Shire is set for March 30 and will feature Shire's upstream and downstream processing areas plus a discussion of some of the advantages and challenges of using disposable technologies in the production of drug products. Check out the Chapter's event calendar for details and to sign up.

As part of the Chapter's continued outreach efforts at our Student Chapters, the Chapter is participating in numerous spring Career Fairs, judging at several poster presentations, and participating in on-campus panel discussions to help students make informed decisions about pursuing careers in the life sciences.

This spring's Annual Poster Competition will be here before you know it. It's being held on Wednesday, April 20 at Worcester Polytechnic Institute's Biomanufacturing Education and Training Center (BETC) in conjunction with the Chapter's April educational program. If you've had to prepare a poster for one of your classes, don't miss this chance to share your work, polish your presentation skills, compete for one of two $500 cash awards and meet a hundred or so local ISPE members who could open a door or two for you on the employment front! You can't win if you don't enter so check out the program flyer and register today!

And finally, the Chapter's scholarship program wants to help pay for the cost of your education. Twice a year, the Chapter awards $12,000 in scholarships as part of the Chapter's commitment to give back to the life sciences community by investing in you. The next application deadline is June 1. Applying is easy and your chances of receiving a scholarship are much higher than you might expect. You can apply online here - be sure to give yourself enough time to complete your application and obtain a written reference before the deadline.

If you need any further convincing of the benefits of being part of an active professional network, check out our new video and hear what some of our Chapter Members have to say: https://vimeo.com/148636910. And remember, students can attend Chapter educational programs and YP social events for free! Hope to see you on campus or at an ISPE event soon!

Industry News In Review

by Jillian Willard, Genzyme, a Sanofi Company

Industry News In Review, a regular feature of the Boston Area Chapter Newsletter, presents news items concerning companies in the pharma, biotech, medical device and related fields, with an emphasis on companies with a local presence and topics of special interest to our readers.

Shire to Combine With Baxalta

Shire and Baxalta announced that the boards of directors of both companies have reached an agreement under which Shire will combine with Baxalta. Under the agreement, Baxalta shareholders will receive $18.00 in cash and 0.1482 Shire American Depository Shares (ADS) per Baxalta share. Based on Shire's closing ADS price on January 8, 2016, this implies a total current value of $45.57 per Baxalta share, representing an aggregate consideration of approximately $32 billion. The value of the offer, as of Shire's January 8, 2016 closing ADS price, represents a premium of approximately 37.5% to Baxalta's unaffected share price on August 3, 2015, the day prior to the public announcement of Shire's initial offer for Baxalta.

This will provide Baxalta shareholders with approximately 34% ownership in the combined company. The parties expect the transaction to close mid-2016. (Source: Shire Website, 11 January, 2016)

Intellia Therapeutics Expands and Launches a New Division

Cambridge-based Intellia Therapeutics has launched a new division, eXtellia Therapeutics, with the intent of focusing resources and research on ex vivo applications of the novel technology, CRISPR/Cas9. As in vivo and ex vivo programs require different competencies in research, manufacturing and commercialization, eXtellia Therapeutics is being launched to accelerate Intellia's efforts in the areas of immuno-oncology, autoimmune and inflammatory diseases while using an ex vivo approach. Intellia will continue its in vivo programs and strategy through a dedicated scientific team.

For ex vivo applications, cells are removed from the patient and edited in culture and then returned to the patient. The in vivo approach packages CRISPR/Cas9 in a delivery vehicle which is administered directly into the patient. CRISPR/Cas9-based gene editing holds great promise across a range of therapeutic applications, including autoimmune and blood disorders, cancer and other genetic-based diseases. It has been shown to be an efficient and precise method for gene editing across multiple cell and tissue types, making it an ideal platform for both ex vivo and in vivo applications. (Source: Intellia Website, 12 January, 2016)

FDA Delays Decision on Sarepta Therapeutics' Eteplirsen

Sarepta Therapeutics, which develops RNA-targeted therapeutics, announced that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of the New Drug Application (NDA) for eteplirsen, for the treatment of Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping. In a notice received from the FDA, the Prescription Drug User Fee Act (PDUFA) date for eteplirsen has been extended to May 26, 2016. The rescheduled date for the Peripheral and Central Nervous System Advisory Committee meeting concerning Eteplirsen has not yet been determined.

The FDA notified Sarepta that its January 8, 2016 submission of 4-year clinical effectiveness data, which included additional six minute walk test (6MWT) and loss of ambulation data compared to a historical control, has been designated as a major amendment to the NDA. The FDA stated that the PDUFA goal date has been extended by three months to allow for a full review of the submission

The FDA has previously granted eteplirsen Priority Review status, which is designated for drugs that provide a treatment where no adequate therapy exists. The FDA also granted Rare Pediatric Disease Designation to eteplirsen, as well Orphan Drug Designation and Fast Track Status. (Source: Sarepta Website, 08 February, 2016)

Epizyme Drug Granted Orphan Drug Designation by FDA

Cambridge-based Epizyme, a clinical stage biopharmaceutical company developing therapeutics for cancer, announced that FDA has granted orphan drug status to the company's first-in-class EZH2 inhibitor, tazemetostat, for the treatment of malignant rhabdoid tumors (MRTs). In December 2015, the company initiated a phase 2 study in adults and a phase 1 study in children with genetically defined tumors, including MRTs. Tazemetostat is also being investigated in an ongoing five-arm phase 2 study in patients with non-Hodgkin lymphoma.

Orphan drug designation provides the sponsor of the drug with eligibility for various development incentives, including tax credits for qualified clinical testing and marketing exclusivity for a period of seven years. Therapies with orphan drug status are also not subject to a prescription drug user fee for the orphan indication.

Currently, treatment of MRT consists of surgery, chemotherapy and radiation therapy, which are associated with limited efficacy and significant treatment-related morbidity. The ongoing phase 2 adult and phase 1 pediatric studies in patients with genetically-defined solid tumors include patients with rhabdoid tumors, other INI1-negative tumors, and synovial sarcoma. (Source: Epizyme Website, 08 February, 2016)

Abbott to Acquire Waltham Based Alere

Abbott and Alere announced a definitive agreement for Abbott to acquire Alere. Under the terms of the agreement, Abbott will pay $56 per common share at a total expected equity value of $5.8 billion. Alere will become a subsidiary of Abbott and the company's net debt, currently $2.6 billion, will be assumed or refinanced by Abbott.

Once the transaction is completed, Abbott will become the leading diagnostics provider of point of care testing. Upon completion of the transaction, the combined business will offer infectious disease, molecular, cardiometabolic and toxicology testing, and will include benchtop and rapid strip tests. (Source: Alere Website, 01 February, 2016)

Editas Medicine Closes IPO

Editas Medicine announced the closing of its initial public offering of 6,785,000 shares of its common stock at a public offering price of $16.00 per share, before underwriting discounts and commissions, including 885,000 additional shares of common stock issued upon the exercise in full by the underwriters of their over-allotment option. All of the shares in the offering were sold by Editas Medicine. The shares began trading on the NASDAQ Global Select Market on February 3, 2016. (Source: Editas Medicine Website, 08 February, 2016)

Mersana Therapeutics and Takeda Expand Partnership

Cambridge-based Mersana Therapeutics and Takeda Pharmaceutical announced that they have entered a new strategic partnership granting Takeda rights to Mersana's lead product candidate, XMT-1522, outside the United States and Canada. The deal also expands an existing collaboration between the companies to provide Takeda with additional access to Mersana's Fleximer® antibody-drug conjugate (ADC) platform and grants Mersana an option at the end of Phase 1 to co-develop and co-commercialize one of these programs in the United States. In addition, the companies will co-develop new payloads for use with ADCs.

XMT-1522 is an investigational, Fleximer-based ADC therapy that targets HER2-expressing tumors, including breast, gastric and non-small cell lung cancers. Mersana anticipates filing an Investigational New Drug application (IND) for XMT-1522 with the FDA in mid-2016.Takeda and Mersana will co-develop XMT-1522, and Mersana will lead execution of the Phase 1 trial. Mersana will retain full commercial rights in the United States and Canada while Takeda will have rights in rest of world.

Beyond development and commercialization of XMT-1522, the expanded partnership also grants Takeda access to additional targets within Mersana's Fleximer-based ADC platform, with Mersana retaining the right to select one program at the end of Phase 1 for co-development and co-commercialization in the United States. Takeda and Mersana will also work together, leveraging Takeda's proprietary small molecule libraries, to identify and develop novel payloads that both parties will be able to use in new ADC therapies.

Takeda signed agreements with Mersana through its wholly owned subsidiary, Millennium Pharmaceuticals, under which, Mersana will receive an upfront payment of $40 million and an additional payment of $20 million upon clearance of the IND for XMT-1522 by the FDA. Subject to the success of the XMT-1522 and ADC programs, Mersana is eligible to receive milestone payments of more than $750 million combined, as well as royalties. Takeda will also invest up to $20 million in equity in future rounds of Mersana financing. (Source: Mersana Website, 03 February, 2016)

FDA Rejects Expansion of Vertex ‘s Kalydeco to New Patient Populations

Vertex Pharmaceuticals announced that it received a Complete Response Letter from the FDA for its supplemental New Drug Application (sNDA) for the use of Kalydeco (ivacaftor) in people with cystic fibrosis (CF) ages 2 and older who have one of 23 residual function mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Kalydeco, which received the FDA's Breakthrough Therapy Designation in 2013, is currently approved in the U.S. to treat people with CF ages 2 and older who have one of 10 mutations in the CFTR gene.

The sNDA for expansion of patient population is based on preclinical data for ivacaftor in residual function mutations, the established clinical profile of Kalydeco and on previously reported data from an exploratory Phase 2a study. In 19 of the 24 patients enrolled in this study, eight of the 23 mutations proposed in the sNDA were represented.

The FDA determined that it cannot approve the application in its present form. Vertex plans to meet with the FDA to determine an appropriate path forward. (Source: Vertex Website, 05 February, 2016)

EU Approves Biogen's Biosimilar Benepali

The joint venture between Biogen and Samsung BioLogics, has been granted European Commission (EC) approval for Benepali, an etanercept biosimilar referencing Enbrel. Benepali has been granted marketing authorization in the European Union (EU) for the treatment of adults with moderate to severe rheumatoid arthritis (RA), psoriatic arthritis, non-radiographic axial spondyloarthritis and plaque psoriasis. Biogen intends to make Benepali available for patients in the coming weeks. Analysis of the primary endpoint showed that Benepali had equivalent efficacy to Enbrel and the safety profile of Benepali was comparable to that of Enbrel throughout the study. (Source: Biogen Website, 16 January, 2016)

AstraZeneca and Moderna Therapeutics to Collaborate on Immuno-Oncology mRNA Therapeutics

AstraZeneca, along with its global biologics research and development arm, MedImmune, and Moderna Therapeutics announced a new collaboration to discover, co-develop and co-commercialize messenger RNA (mRNA) therapeutic candidates for the treatment of a range of cancers. The collaboration is in addition to the agreement announced by the companies in 2013 to develop mRNA Therapeutics for the treatment of cardiovascular, metabolic and renal diseases as well as selected targets in oncology. mRNA-based therapies enable the body to produce therapeutic protein in vivo, opening up new treatment options for a wide range of diseases that cannot be addressed today using existing technologies.

Under the terms of the new agreement, AstraZeneca and Moderna will collaborate on two specific immuno-oncology programs. Moderna will fund and be responsible for discovery and preclinical development of product candidates, with the aim of delivering one Investigational New Drug (IND) application-ready molecule for each of the two programs. Moderna's efforts will be led by its oncology-focused venture, Onkaido. AstraZeneca will be responsible for early clinical development, led by MedImmune, and Moderna and AstraZeneca will share the costs of late-stage clinical development. The two companies will co-commercialize resulting products in the US under a 50:50 profit sharing arrangement. AstraZeneca will lead ex-US commercialization efforts, with Moderna receiving tiered royalties.

Under the companies' original strategic agreement, AstraZeneca holds exclusive access to select any target of its choice in cardiometabolic diseases, as well as select targets in oncology, over a period of up to five years for subsequent development in mRNA. Several projects are progressing towards clinical development under the arrangement, and a first-in-human study is expected to commence in late 2016. (Source: Moderna Therapeutics Website, 11 January, 2016)

Novartis to Collaborate with Surface Oncology

Novartis and Cambridge-based Surface Oncology announced a new strategic alliance and licensing agreement. The agreement gives Novartis access to four pre-clinical programs that target regulatory T cell populations, inhibitory cytokines, and immunosuppressive metabolites in the tumor microenvironment. These programs will be explored as monotherapies and in combination with other complementary therapies in Novartis' immuno-oncology and targeted therapy portfolios.

Under the terms of the agreement, Surface is eligible to receive up to $170M in upfront, equity, and near-term milestone payments. Novartis will gain exclusive access to Surface's current pipeline of novel cancer immunotherapies, including an exclusive worldwide license to its leading program and options to license up to three additional programs from the existing portfolio, exercisable at IND. Surface is eligible to receive clinical and commercial milestones and up to double-digit royalties on product sales. Surface also has the option to retain U.S. development and commercialization rights for at least half of the collaboration's programs. (Source: Novartis and Surface Oncology Websites, 11 January, 2016)

Charles River Laboratories to Acquire WIL Research

Charles River Laboratories announced that it has entered into a definitive agreement to acquire WIL Research for approximately $585 million in cash, subject to customary closing adjustments.

WIL Research is a premier provider of safety assessment and contract development and manufacturing (CDMO) services to biopharmaceutical and agricultural and industrial chemical companies worldwide. Acquiring WIL Research will enhance Charles River's position as a leading global early-stage contract research organization (CRO) by strengthening its ability to partner with global clients across the drug discovery and development continuum.

James C. Foster, Chairman, President, and Chief Executive Officer of Charles River Laboratories, commented, "In addition to meeting our disciplined acquisition criteria, WIL Research is an exceptional strategic fit for Charles River because it incorporates the key attributes we require in an acquisition: high-quality services, scientific expertise, complementary capabilities, and access to growing end markets. The acquisition will also expand our geographic footprint, particularly in continental Europe, providing needed capacity to meet current and future demand and enabling Charles River to provide a broader range of services proximate to our global clients." (Source: Charles River Laboratories Website, 07 January, 2016)

Alexion Launches Charitable Program in New Haven

Alexion Pharmaceuticals and The Community Foundation for Greater New Haven announced today the launch of "Here in New Haven", a charitable giving initiative to support 30 local non-profit organizations dedicated to strengthening the greater New Haven community. The program coincides with Alexion's move to its new global headquarters at 100 College Street. Through this initiative, Alexion will provide a $1,000 grant each day over a period of 30 business days, culminating on February 29, 2016, which is Global Rare Disease Day.

Recipients of the Here in New Haven grants were selected from a list of New Haven-serving non-profits profiled on giveGreater.org®, an online resource for learning and giving provided by The Community Foundation. Each organization will be invited to the opening of the new Alexion global headquarters, which will include a building dedication and remarks from both Alexion and Connecticut state and local officials. (Source: The Community Foundation for Greater New Haven Website, 19 January, 2016)

Regulatory & Legislative Highlights

by Deepen Joshi, Sunovion Pharmaceuticals

Regulatory & Legislative Highlights, a regular feature of the Boston Area Chapter Newsletter. It reviews recent actions by the FDA and other regulatory agencies and governmental bodies, both federal and regional, with the potential to impact the pharma, biotech and device industries, and related fields.

FDA Approves Empliciti from BMS for Multiple Myeloma

The FDA has granted approval for Bristol-Myers Squibb drug Empliciti (elotuzumab) in combination with two other therapies to treat people with multiple myeloma who have received one to three prior medications. Multiple myeloma is a form of blood cancer that occurs in infection-fighting plasma cells (a type of white blood cell) found in the bone marrow. These cancerous cells multiply, produce an abnormal protein and push out other healthy blood cells from the bone marrow. This disease may result in a weakened immune system, and cause other bone and kidney problems.

Empliciti activates the body's immune system to attack and kill multiple myeloma cells. It is approved in combination with another FDA-approved treatment for multiple myeloma called Revlimid (lenalidomide) and dexamethasone (a type of corticosteroid).

The FDA granted breakthrough therapy designation for this application, which is granted when a drug is intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints. Empliciti also received priority review and orphan drug designations. (Source: FDA Website, 30 November, 2015)

Alexion's Kanuma Wins FDA Approval to Treat Rare Enzyme Disorder

The FDA has approved Kanuma (sebelipase alfa) as the first treatment for patients with a rare disease known as lysosomal acid lipase (LAL) deficiency. Patients with LAL deficiency (also known as Wolman disease and cholesteryl ester storage disease [CESD]) have no or little LAL enzyme activity. This results in a build-up of fats within the cells of various tissues that can lead to liver and cardiovascular disease and other complications.

Wolman disease often presents during infancy (around 2 to 4 months of age) and is a rapidly progressive disease. Patients with Wolman disease rarely survive beyond the first year of life. CESD is a milder, later-onset form of LAL deficiency and presents in early childhood or later. Life expectancy of patients with CESD depends on the severity of the disease and associated complications. Wolman disease affects one to two infants per million births, and CESD affects 25 individuals per million births. (Source: FDA Website, 08 December, 2015)

FDA Approves New Oral Therapy to Treat ALK-Positive Lung Cancer

The FDA has approved Alecensa (alectinib) to treat people with advanced (metastatic) ALK-positive non-small cell lung cancer (NSCLC) whose disease has worsened after, or who could not tolerate treatment with, another therapy called Xalkori (crizotinib). Alecensa is marketed by Genentech and Xalkori is marketed by Pfizer.

Lung cancer is the leading cause of cancer death in the United States, with an estimated 221,200 new

diagnoses and 158,040 deaths in 2015, according to the National Cancer Institute. An ALK (anaplastic lymphoma kinase) gene mutation can occur in several different types of cancer cells, including lung cancer cells. ALK gene mutations are present in about 5 percent of patients with NSCLC. In metastatic cancer, the disease spreads to new parts of the body. In ALK-positive NSCLC metastatic patients, the brain is a common place for the disease to spread. Alecensa is an oral medication that blocks the activity of the ALK protein, which may prevent NSCLC cells from growing and spreading.

Alecensa was approved using the accelerated approval regulatory pathway, which allows the FDA to approve products for serious or life-threatening diseases based on evidence that the product has an effect on an outcome that is reasonably likely to predict clinical benefit. In the case of Alecensa, the tumor response to treatment, along with the duration of response, provided this evidence. Under the accelerated approval requirements, a confirmatory study is required to verify and describe the clinical benefit of Alecensa. (Source: FDA Website, 11 December, 2015)

FDA Approves AstraZeneca's Zurampic to Treat Gout

The FDA has approved Zurampic (lesinurad) to treat high levels of uric acid in the blood (hyperuricemia) associated with gout, when used in combination with a xanthine oxidase inhibitor (XOI), a type of drug approved to reduce the production of uric acid in the body.
Zurampic works by helping the kidney excrete uric acid. It does this by inhibiting the function of transporter proteins involved in uric acid reabsorption in the kidney. Zurampic is manufactured by AstraZeneca Pharmaceuticals.

Zurampic has a boxed warning that provides important safety information for health care professionals, including the risk for acute kidney (renal) failure, which is more common when used without an XOI and with higher than approved doses of Zurampic. The FDA is also requiring a postmarketing study to further evaluate the renal and cardiovascular safety of Zurampic. (Source: FDA Website, 22 December, 2015)

FDA Approves First Drug to Show Survival Benefit In Liposarcoma

The FDA has approved Halaven (eribulin mesylate), a type of chemotherapy, for the treatment of liposarcoma (a specific type of soft tissue sarcoma) that cannot be removed by surgery (unresectable) or is advanced (metastatic). This treatment is approved for patients who received prior chemotherapy that contained an anthracycline drug. Halaven is marketed by Eisai.

Serious side effects from treatment with Halaven may include a decrease in white blood cell count, which can increase the risk of serious infections that could lead to death; numbness, tingling or burning in the hands and feet (neuropathy); harm to a developing fetus; as well as changes in heartbeat (QTc prolongation), that may also lead to death.

The FDA granted the Halaven application priority review status, intended to facilitate and expedite the development and review of certain drugs in light of their potential to benefit patients with serious or life-threatening conditions. Halaven also received orphan drug designation, which provides incentives such as tax credits, user fee waivers, and eligibility for exclusivity to assist and encourage the development of drugs for rare diseases. (Source: FDA Website, 28 January, 2016)

FDA Approves Zepatier for Treatment of Chronic Hepatitis C

The FDA has approved Zepatier (elbasvir and grazoprevir) with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adult patients. Zepatier is marketed by Merck & Co.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take several years. Some people with chronic HCV infection develop cirrhosis over many years, which can lead to complications such as bleeding, jaundice, fluid accumulation in the abdomen, infections or liver cancer. According to the Centers for Disease Control and Prevention, approximately 3 million Americans are infected with HCV, of which genotype 1 is the most common and genotype 4 is one of the least common. (Source: FDA Website, 28 January, 2016)

New Members

Logan Almquist, University of New Hampshire

Chaitra Belgur, B.E, Northeastern University

Carl Bradbury, DPS Engineering

Michael Carlson, CHE, Genzyme

Adam Russell Carr, Brigham Young University

Robert Castro, EMD Millipore

Zhidan Chen, Northeastern University

Tyler Cole, Northeastern University

Elena Conroy, Worcester Polytechnic Institute

Paul Cook, PhD, Integrated Project Management

Jamie Curran, Bristol-Myers Squibb

David Didio, M.S., Shire Pharmaceuticals

William Dolan, Advanced Control Associates, LLC

Brooks Doten, Middlesex Community College

Tianna Edwards, University of Massachusetts Dartmouth

William H. Farrow, III, Siemens Healthcare Diagnostics

Jim Fortune, Ocular Therapeutix, Inc.

Michael Frempong, Genzyme

William Garvey, William Garvey and Associates

Ted Haley, IV, Alfa Laval Tank Equipment Inc.

Nerses Haroutunian, University Massachusetts-Amherst

Devin Hersey, Barry Wehmiller Design Group

Jeffrey Holyoke, Takeda Pharmaceuticals Inc.

Jacqueline Iannuzzi, Ironwood Pharmaceuticals

Gayatri Kasi, Worcester Polytechnic Institute

Swetha Krishnan, Sanofi

Kalyn Lai, Northeastern University

William Lichtman

Ben Maimon, Massachusetts Institute of Technology

Chandrasekar Marimuthu, B.E., Structure Tone Inc

Farroukh Mohammed, Northeastern University

Angie Moreno, Ph.D, 3M Purification Inc.

Francis OLoughlin, East Pond Consulting

Krishnan Parameswaran, Physical Sciences Inc.

Christine Parrington, AQUIS

Priya Prabakaran, Northeastern University

Prudhvi Raju Pusapati, Northeastern University

Paul Richard, Donaldson Company, Inc.

Roland Rivera, AAS, BA, Rhodes Technologies

Ian Rose, Pfizer

John F. Ryan, ProPharma Group

Nitin D. Satav, EMD Millipore

Curtiss Paul Schneider, Ph.D., Biogen

Brian Schuster, Seres Therapeutics

Shivaranjani Shivalingaiah, Shire

Shelby Nicole Silvia, University of New Hampshire

Janeen SkutnikWilkinson, Biogen Idec

Rachana Deven Somaiya, Northeaster University

Megha Suresh, M.S., Northeastern University

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Nicholas Tancrede, University of New Hampshire

Jeffrey J. Tantum, Middlesex Community College

Heena Thakkar, Northeastern University

Jennifer Tucker, CrossPoint Engineering

Chad Walker, Worcester Polytechnic University

Jing Wang, Northeastern University

Matthew Wasdyke, DPS Engineering

David Wenzel, BSME, Admix Inc

Di Xu, Northeastern University

Qing Yu, Northeastern University

Yan Zhao, Northeastern University

Member Anniversaries

Join us in celebrating the 5, 10, 15 and 20+ year anniversaries of Boston Area Chapter Members. Congratulations to all of our long term Chapter members - your loyalty helps make us successful, year after year!

Over Twenty Years

- Saboo Aghababayan, Genzyme Corp (24 years)
- Richard F. Caires, Jr., Shire HGT (24 years)
- Ronald C. Case, Aztec Technologies, Inc. (22 years)
- Charles L. Cooney (24 years)
- Michael B. Cronin, Alexion Pharmaceuticals (27 years)
- Edward F. Dean, III, Eagle Electrical Supply Co (22 years)
- Brian M. Hagopian, CPIP, Clear Water Consulting, Inc. (24 years)
- Andrew R. Hahn (22 years)
- David G. Harney, Microfluidics (24 years)
- Mitchell I. Hollander, Lantheus Medical Imaging (25 years)
- Jerome E. Justin, Genocea Biosciences, Inc (26 years)
- Howard L. Levine, PhD, BioProcess Tech Consultants, Inc. (23 years)
- Glenn J. Martin, GM, LLC (21 years)
- Peter A. Petrillo, Millennium Facilities Resources Inc (22 years)
- Tim J. Potvin, PE, Quality Air Control (23 years)
- Thomas A. Ramundo, New England Controls Inc (25 years)
- John J. Rozembersky, Rozembersky Group (24 years)
- Gregory M. Ruklic, Independent (24 years)
- Jack N. Wentz, Lantheus Medical Imaging (24 years)
- Jay F. Zaino, GxP Automation LLC (22 years)
- Gary V. Zoccolante, BSME, Evoqua Water Technologies LLC (24 years)

Twenty Years

- John R. Butterfield, Hallam Associates Inc
- George R. Skillin, Pfizer

Fifteen Years

- Douglas Brenner
- Eric D. Felz, Shire
- Colin M. O'Sullivan, D L Thurrott

Ten Years

- Gary Barbin, Lantheus Medical Imaging
- Leo T. Bedard, Genzyme Corp
- John Hamel, Parsec Automation Corporation
- Sheldon M. Lathrop, Celsius Technologies
- Jim Rice, Genzyme Corp
- Robert Wilkie, TRG Builders LLC

Five Years

- Nickolas A. Brings, MBA, Biogen Idec
- Michael D. DiModica, Sanofi Genzyme
- Lindsay Gwyther, Genzyme Corp
- Blake W. Hughlock, Barry-Wehmiller Design Group
- Niranjan S. Kulkarni, CRB
- David E. Rabon, ASET, BSIS, MSIS, Pfizer
- Christopher Welch, Lantheus Medical Imaging
- Robert D. Whipple, Pfizer Inc

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