

NEWSLETTER







www.ispeboston.org

May 2009, Volume XIX, No. 3

Return to the Table of Contents | Printing Instructions



President's Message: Yes, you can innovate and save money at the same time and so can we...

Dear Boston Area Chapter ISPE Members,

Just like everyone else, ISPE is seeing the effects of the downturn in the economy. Not as many people are attending the large conferences in Tampa or Washington, D.C. and Chapters across the country also have experienced fewer people at events.

As companies tighten their belts, the emphasis changes from ambitious technical innovation to lower-risk, cost-saving measures. There is a natural reluctance to add new capacity, so capital project spending is reduced or delayed. Our new, more liberal President is encouraging spending on "green" projects that are "shovel-ready," which doesn't sound much like pharmaceuticals, does it? So what is a poor engineer to do?



It turns out you can still innovate AND save money at low risk if you think about items that save money for your employer. In fact, this is a golden opportunity to overcome those QA objections to any change if you can demonstrate real savings. For example, you can look at ways to reduce or shut off HVAC when the facility is not in use. You can look at diaphragm valve materials other than Teflon which are cheaper, more durable and do not require replacement as often. You can more aggressively stretch out maintenance intervals in areas that are not related to product quality and you can substitute variable frequency drive motors for single-speed motors in applications where you can save energy by doing so.

Your Chapter has been thinking along these lines as well. To innovate and save money at low risk we have reduced the cost of programs by having them in venues where we do not have to pay a room rental fee and do not have to hire expensive caterers; and those that are easier to get to with free or reduced-fee parking. We have had more programs on "softer" subjects such as Business Partnering and Managing a CMO, Marketing Yourself, and Leadership, in an effort to provide better information for the times we live in. Not to mention the Summer Social coming up in June, which will once again be (nearly) free, and the two-day training on Biotechnology and Cleaning Validation, available locally or also for your company exclusively.

Not all of these ideas will work, but rest assured that your Chapter remains on sound financial footing and will continue to offer programs and events to meet your needs. If you have ideas on programs we have not offered or would like to volunteer, please email us at ispe@camihq.com or call 781-647-4773 to speak to a live person. We need volunteers now more than ever!

Sincerely,

Doyle Johnson

President, ISPE Boston Area Chapter

Upcoming Chapter Events: Mark Your Calendars!

Thursday, June 11, 2009

Summer Social and Volunteer Appreciation Night

Have fun networking with fellow members. Taste Boston Beer Works great summer brews, play pool, have dinner and even have a chance to win great raffle prizes.

Boston Beer Works, Canal Street, Boston

CLICK HERE TO REGISTER ONLINE

Complete Facility Automation & Compliance Solutions for the Life Science Industry



- Turnkey HVAC / Facility Automation
- GMP Monitoring / Process Integration
- · Commissioning / Validation Services
- Technology Project Management
- UL508A Panel Fabrication Facility
- Rockwell Automation VFD Products
 25 Mulberry Larie
 Pelitam NF 03076
 (605) 998-48255
 (605) 998-4825
 (778) 860-7900

www.GxPAutomation.com





Tuesday, June 16, 2009

Forefronts in Bioengineering: Stem Cells, Soft Body Robots, Bio-Optics

Speaker:

Dr. David Kaplan, endowed chair, professor and chair of the Department of Biomedical Engineering, Tufts University

Tufts Gordon Institute, Medford, MA

CLICK HERE TO REGISTER ONLINE

Monday, August 17, 2009 7th Annual Golf Tournament

Purchase a Foursome now! There aren't many left.

Ferncroft Country Club, Middleton, Massachusetts

Click Here for a REGISTRATION FORM

Wednesday, October 7, 2009 Annual Product Show

Gillette Stadium Clubhouse, Foxborough, Massachusetts

REGISTRATION IS OPEN FOR EXHIBITOR REGISTRATION

MIT Professor Sheds Light on Magnetically-Enhanced Separations for Biopharm Processing

by Lee Ward, Rockwell Automation, with assistance from John Sheridan, PMA Consultants

Dr. Alan Hatton, Ralph Landau Professor of Chemical Engineering Practice and Director, David H. Koch School of Chemical Engineering Practice at MIT, treated a rapt audience to a lesson in pure science on March 11th. This ISPE evening program was co-sponsored by MIT Professional Education, with Executive Director Bhaskar Pant and Dawna Levenson, Dee Moore and Tavish Baker in attendance. Heralding from the distant reaches of South Africa, Dr. Hatton is a graduate of the University of Natal in Durban and moved into research in Pretoria. Later he furthered his studies at the University of Wisconsin where he completed his PhD in Chemical Engineering. His research interests are in the exploitation of colloidal phenomena in chemical processing applications and include responsive surfactants and gels, reactive fibers and fabrics, and functionalized magnetic nanoparticles and nanoparticle clusters.

His research and the subject he presented would be considered by most to be "way over my head." However, in this case, Dr. Hatton took the subject of "magnetic separation" and brought a glimmer of light into the darkness. When most audiences hear the term "nanotechnology" their eyes glaze over and their attention quickly drifts away - they believe the subject exists only in the minds of so many scientists. However, those who attended Dr. Hatton's presentation were quickly immersed in a subminiature world of particle separation and purification, and introduced to terms such as "colloidal materials" and "magnetophoretic." And with a brief explanation of the goals to be achieved through the application of this technology, the audience was able to draw a parallel to existing methods of harvesting common in the practice of chromatography most of us are already familiar with.

Dr. Hatton was able to describe the issues that exist with the accepted norms for separation methods such as media loss, cross contamination, and throughput; and then went on to describe the limitations of the adsorptive separation methods. As a non-chemist, I could easily appreciate the challenges that large-scale manufacturers face, with enormous volumes of liquid suspension feverishly fermenting in a vessel for a period of time only to reach the bottleneck of harvest separation.

The answer, it seems, lies in the application of nanotechnology in the form of magnetically sensitive particles that hold a specific level of attraction to a desired protein that is existing in that liquor. I learned that introducing a suspension of nanoparticles with a distinctive protein signature to the liquor caused the target protein to attach to the nanoparticles. Then, subjecting the entire outflow to a high magnetic field allows the particles loaded with protein to be captured and undesirable cell debris to pass through the system. The separation is completed by separating the protein from the particle media and then the particles themselves are recovered by removing the magnetic field.

It sounds simple. But then we delved into the physics of the principle, including how aqueous solutions of various polymers to the magnetite aggregate are able to vary the effectiveness of the separation process. All of which became clearer with the aid of the many excellent diagrams and graphs that Dr. Hatton used for illustration. The presentation culminated with the practical applications that have been developed and included slides of some of the manufactured equipment that is able to perform this miraculous feat.

Dr. Hatton gave credit to the students and research fellows who have worked tirelessly to develop this theory into what is now a tangible alternative to traditional separation technologies, the advantage being cost and productivity which immediately begins to impact that ever-important question of ROI. His presentation was followed by an interactive Q&A session, where many attendees took advantage of this time to clarify their understanding of the incredible amount of information he covered in such a short period. I thoroughly enjoyed the program and left the room feeling a little bit more educated in a new realm. After all, one day I may be a consumer of the products borne from the process Dr. Hatton so ably described.

Does Automation Technology Change?

ALWAYS!

Superior Controls is a leader in providing automation and information systems to the BioPharma Industry. We have the resources to meet your automation needs and our highly experienced engineers are attuned to the muances of FDA validation requirements and the latest technologies available.

After All, Change is Exciting.

www.superiorcontrols.com 1-800-639-1736.





components for your compliance with cGMP, validation, ASME BPE and USP Class VI requirements.

BPE fittings and tubing
 In-house custom sanitary hose assemblies
 Class VI gaskets, tubing & molded products
 Diaphragm and ball valves

Pressure and temperature instrumentation



208 High St., Randolph, MA 02368 800-249-9337 • sales@tekspf.com Visit us online at www.tekspf.com







April Workshop Helps Members Learn Effective Networking Skills

by Ed Nickerson, GMP Piping, Inc. with photo by Doyle Johnson, MassBioLogics

At a time when companies are downsizing and state agencies are struggling to help, the Boston Area Chapter did its part by hosting a "Members only" networking event at the F.W. Webb corporate headquarters in Bedford on April 9th. Developed by meeting managers Monique Sprueill and Ric Feldt, and hosted by Ted Haley of F.W. Webb, the event focused on something many people struggle with: the skills and techniques of "Marketing Yourself," or networking effectively to sell your own unique skill set. Guest speakers included training and management consultants Linda Trowbridge and Bob Vear of Change Dynamics, Inc. who presented an exciting and interactive learning session that covered networking basics; and Bob Steininger, Senior Vice President, Manufacturing at Acceleron, who described the hiring process from a real world perspective and outlined what hiring managers look for in today's tight job market.

Monique sees the current downturn in the economy as an opportunity for ISPE to assist its members in transitioning from one role or company into something new and exciting. In addition, many of us (myself included) simply need to brush up on basic networking skills in order to feel more comfortable meeting someone new and engaging in conversation. It's these skills that Linda and Bob came to review, discuss and practice with program participants. Their presentation covered many topics, from the definition of "marketing yourself" to how to get started and the do's and don'ts of successful networking. On the topic of first impressions, they used a funny skit to break the ice and open up discussions among participants. By the end of the presentation, everyone seemed completely



Participants practice networking skills during breakout session.

comfortable sharing opinions and ideas, a great example of effective networking in action.

When planning this session, Ric and Monique agreed it was essential to add a real world, hiring manager's perspective to the training provided by Linda and Bob. Bob Steininger of Acceleron filled the bill by sharing the highs and lows of interviewing candidates in the current economy. Bob emphasized that integrity, self confidence and subject knowledge are only some of the qualities hiring professionals look for in a candidate. Today it is critical for candidates to know as much as possible about the hiring company - it products, processes and history - before meeting a hiring manager so they can explain how their skills are well-suited to the company's needs. That will go a long way toward convincing the hiring manager that they are a good fit for the position and the company as a whole.

The three presentations together presented a great introduction to the skills needed to successfully market yourself.





Keeping our eye on the valve





In the end, "it's not what you know but who you know," because marketing yourself is about building lasting relationships that will lead to new opportunities.

I met many interesting people at this event and wish them all well in their future endeavors. Thanks to Monique, Ric and the Chapter Board of Directors for this practical, skill-building session and to Ted Haley and F.W. Webb for hosting the event. And keep an eye out for additional workshops like this one - Monique, Ric and the Board are working hard to get follow up sessions scheduled for later this year.

<u>Program on Strategies to Survive the Recession Draws Members to</u> <u>Cambridge</u>

by Debbie Crooke, Thompson Consultants, Inc. with photos by Sam Liggero, Tufts Gordon Institute

On April 21st, the Boston Area Chapter presented a seminar on "Strategies to Survive the Recession: Business Partnering and Contract Manufacturing." The session was presented by Peter Latham and Susan Dexter, both from BioPharm Services. Peter opened with a discussion on "Partnering with Larger Companies" and Susan discussed "Managing a Project with a Contract Manufacturing Organization (CMO)."

Partnering with Larger Companies



With the shortage of investment capital, even for many venture capital firms, many early stage biotech firms have found that partnering with larger companies can be an attractive alternative. It turns out that there are many synergies between large and small firms that make these deals attractive beyond just the financial support. First, smaller firms are typically great at innovation, which can often be more difficult for large firms. On the other hand, large firms are great at implementation, at which smaller firms are often less adept. Therefore, by combining their efforts, firms can leverage each other's strengths while softening their weaknesses.

Meeting Manager Joyce Chiu introduces the evenings speakers, Pete Latham and Susan Dexter, below. So, if this is the right solution, how should you go about finding the right partner and how should you structure the deal? Well, unfortunately, there is no "right" way to do it. What works for you and your partner firm may not be best for others. Peter presented several examples where the same approach had very different outcomes - one excellent and the other "perceived as not

very successful." How you structure the deal and manage the relationship often has a greater impact on whether it will be successful or not. Peter discussed the following three approaches:

• Acquisitions - best when you have sales .

• Joint Ventures - can be challenging as you are continually worrying about how to break it up when you are done.

 Government deals - generally very structured and welldefined; however, what you gain in clarity, you often loose in profitability.



So, once you have decided to pursue a partnership, how do you find a partner? Like many other things, relationships are critical. Find people who know the people you are

interested in working with; or go to where you know they will be and try to meet them. Cold calls can work but they are much harder than personal introductions.

Once you have an audience, now what? Peter indicated that credibility is critical when taking your product to market. Stand in the buyer's shoes and think about the deal from their side of the table. Remember, people make decisions and people buy technologies. Large companies are worried about risk - they will look at what could go wrong if they buy or what could go wrong if they don't buy.

It is also important to remember that if you do sell your technology to a larger firm, they will likely tweak your product and then take credit for it. Though this may be difficult, it is an important step in the process by which the larger company takes ownership of the product, gets invested in its success and ensures it gets the priority and focus it requires.

Setting clear goals with benefits for each party is very important. Also key to making the relationships and the deals work is to enlist and maintain the support of a senior person in the larger company as well as an excellent project manager.

Unfortunately, many large companies are currently looking for bargains. Still, don't be afraid to ask for fair value - after all, you took the risk on the project. Typical "fair" value is 5x sales or 9-10x EBITDA. If you can get 5x sales, you should do it. Plus there are lots of other deals that you can reference to help you know what kind of a deal you can expect.

Managing a Project with a Contract Manufacturing Organization (CMO)

Working with a CMO can not only reduce your upfront facilities costs but can also allow you to move forward more quickly. Once you have decided to explore working with a CMO, you first need to set up the parameters under which you will work. Developing a matrix to measure against will be important. This must include clear milestones as well as the project scope - size, budget and time line.



Previous Issues

May 2009. Volume XIX.... (9) April 2009. Volume... (11) February 2009. Volume.... (10) December 2008. Volume.... (13) October 2008. Volume.... (12) August 2008. Volume.... (10) June 2008. Volume.... (11) April 2008. Volume.... (10) February 2008. Volume.... (10) December 2007. Volume.... (13) October 2007. Volume.... (10)



Even more critical is gaining an understanding of the team members who will be participating in the project - great individuals don't always make

great teams. The team members' goals must be fully in alignment - if they create them "together," they own them. And finally, it is important that you are focused on the big picture, even while you are mired in the details getting work done.

Next you must evaluate the various CMOs and pick the right one for your firm. The best way to evaluate CMOs is to perform a gap analysis that is focused on three key areas:

- Technical Issues If there is too big a difference in how they handle the technical issues, it is best to walk away.
- Quality Big gaps here are also important to note but some of this could be balanced with a strong quality person on your team.

 Interpretation of GMP - This is one area where a gap analysis has often shown a difference that could have a major adverse impact on your project's success. Teams' regulatory and quality groups should talk about FDA or other regulatory guidelines and agree on interpretation in order to ensure alignment.



Two of the many attendees looking for tips on successful business partnering.

Sometimes the CMO will perform a gap analysis of the client company, evaluating the data they come in with and the quality of that data, to be sure that the project will have a successful outcome. It is critical to the CMOs success that the client has clear, written processes in place. They must also understand where some of the holes and hurdles are before leaving the benchtop because it is far more costly and time consuming to correct issues during manufacturing.

One example Susan shared related to insufficient stability studies. She had a project where it was determined during the manufacturing process - that the product was unstable when the containers it was stored in were exposed to vibration during shipping and handling. Correcting this after the manufacturing process was in progress proved to be quite costly.

In summary, working with a CMO can be an excellent way to conserve time and money. However, like anything else, being clear about your goals and needs, effectively communicating them and then managing the process is essential to success. Also critical is choosing the right team - both your in-house team and the CMO.

Boston Area Chapter Young Professionals Sponsor Their First Event

by Dan Ramsey, Commissioning Agents, Inc., with photos by Chris Ciampa, Thermo Fisher Scientific

On April 29th, the ISPE Boston Area Chapter Young Professionals sponsored their first educational event. The event was hosted by Shire and included dinner and two educational seminars and was well attended by both members of the Young Professionals group and other Chapter Members. The Young Professionals is a new organization within ISPE that was formed to foster the ideas and professional needs of individuals who consider themselves new in their careers or new to the biotechnology and pharmaceutical industry. The primary focus of the Young Professional organization is education, career/professional development, and networking.



The first presentation of the evening was an educational seminar lead by Lou Traglia of Commissioning Agents who spoke on the topic of "Biotechnology." Lou covered the major operational and functional steps in the biotechnology process including current and future

Chapter Past President and YPI liaison Dave Novak discussing the local industry with attendees.

developments within the biotech industry. The presentation contained a question/answer and discussion forum on topics such as risk-based validation, higher-titer processes and the use of process analytical technology that had great audience participation.



Attendees a moment to relax during a break in the action.

The second speaker was Kevin Lynch from Shire, who also hosted the event. Kevin discussed biotech basics with a focus on career opportunities and developments within the industry. As the director of manufacturing at Shire, Kevin had a good perspective on the current trends and needs of the industry. He highlighted changes within the industry and outlined the different areas for individuals to focus on in order to enhance their professional development.

The Young Professionals are working on developing a series of upcoming events including educational seminars, tours and social activities. If you would like more information or would like to participate in the group, please contact the Boston Area Chapter office

Industry News In Brief

by Patti Charek

Novartis to Expand in Cambridge

The pharmaceutical giant Novartis AG is planning to build a new facility on Massachusetts Avenue in Cambridge, in the shadow of the MIT. Novartis, based in Basel, Switzerland, has signed a long-term lease for property at 181 Mass Ave., which is currently a two-acre parking lot owned by MIT. Already Cambridge's largest employer, Novartis is likely to build a research facility on the site, although no final decisions have been made. "We're committed to Cambridge. This is a long-term investment," said Mark Fishman, president of the company's institute for biomedical research. "We have found it particularly beneficial to have the relationship with MIT, Harvard, and the hospitals in the neighborhood."

Novartis already occupies more than a million square feet in Cambridge, much of it in the former Necco candy factory near Central Square. The location is home to its global research unit, and Novartis has recently located its vaccines and diagnostics division in Cambridge, too. Altogether it has about 2,000 employees, split among 10 buildings, near Kendall Square and in research parks along Massachusetts Avenue.

The Cambridge expansion bucks the trend of biotech firms and other companies moving out of the urban core to the suburbs, where office space is generally cheaper and businesses have more flexibility to expand and to customize facilities. Novartis executives said the Cambridge location gives them access not only to new recruits at MIT and Harvard, but opportunities to collaborate with researchers at universities and teaching hospitals.

Novartis has an array of cancer and diabetes drugs being developed in Cambridge that could be submitted for approval in the next few years. The firm's executives would not disclose details of the 181 Massachusetts Ave. lease, saying only that it is a long-term contract and that the company eventually intends to build on the property. It has not decided on details for a new building but has hired the Boston real estate firm Leggat McCall to help plan the project.

Steve Marsh, the head of real estate for MIT, said the property could accommodate a building of about 250,000 square feet. He said the university, which began leasing space to Novartis when it first moved to Cambridge, intends to continue building in the area.

"In general, MIT has been trying to continue building an innovation cluster in and around Cambridge and the MIT campus," he said. "It's worked for area business and for the City of Cambridge in terms of tax dollars." MIT recently won city approval to construct a 450,000-square-foot research building on Main Street that it intends to lease to private companies. (Source: Casey Ross, The Boston Globe, 8 May, 2009)

Roche/Genentech Drug Fails to Prevent Colon Cancer in Clinical Trial

The drug Avastin failed to prevent colon cancer from recurring in a clinical trial, the drug's manufacturer, Genentech, said. The results of the trial had been closely watched because a success would have paved the way to a new use of the drug, potentially increasing sales by billions of dollars a year. Now those efforts will be set back, and it appears that Roche may have paid more than it needed to acquire Genentech in March. However, Genentech and Roche said they would continue to try to develop Avastin for use in early-stage cancer.

Avastin is already one of the world's biggest-selling cancer drugs, with sales of \$2.7 billion in the US alone last year. But it is approved now only for late-stage colon, breast and lung cancers. In that use, trials have shown the drug can prolong life by up to a few months. The new trial was an attempt to use it earlier in the course of the disease, right after surgery to remove the tumor. The hope of such so-called adjuvant therapy is to prevent the cancer from coming back at all, effectively curing the patient.

The trial had about 2,700 patients who received six months of the standard chemotherapy or six months of that chemotherapy plus a year of Avastin. The study, sponsored by the National Cancer Institute, measured how many patients were alive and free of cancer over time. The existing chemotherapy already keeps about 70% of colon cancer patients free of the disease three years after their surgery. So improving on that significantly was considered a difficult hurdle. Genentech had rated the chance of success in the trial at 61 percent and Roche at 55 percent.

The trial played a prominent role in Roche's acquisition of the part of Genentech that it did not already own for \$46.8 billion. Roche had wanted to get the deal done before the results of the trial were announced because a success would have sent Genentech's stock soaring. A failure would have sent Genentech's stock down significantly. So it now looks as if Roche could have paid less if the results had come out before it completed the deal. When it was fighting to remain independent or to get Roche to make a higher offer, Genentech argued that Avastin sales could quadruple to \$10 billion by 2015 if the drug could be used for early-stage colon, lung and breast cancers. (Source: Andrew Pollack, New York Times, 23 April 2009)

20 Biogen Idec Drugs in Advanced Trials

Biogen Idec said it has 20 new medicines in advanced human trials, including treatments for multiple sclerosis, cancer, and Parkinson's disease. At least six of the new medicines have reached the final tests generally required for US marketing clearance.

Biogen, the world's largest maker of multiple sclerosis drugs, will have two MS medicines in late-stage trials by the end of this year, including a new version of its top-selling Avonex drug and a pill, called BG-12. Avonex, an injectable medicine, generated \$2.2 billion last year, accounting for more than half of Biogen's \$4.1 billion in revenue. Its fastest-growing product is the MS drug Tysabri, which produced worldwide sales of \$813 million for Biogen and partner Dublin-based Elan Corp.

Biogen now has more than 60 drug programs in development covering 15 indications, according to the company's

statement. Biogen's new version of Avonex is designed to offer patients more convenient dosing. Avonex is an interferon compound. The new version is pegylated, meaning it is altered to increase the time the drug circulates in the body. The company is also testing an experimental leukemia treatment, lumiliximab, and a Parkinson's drug, BIIB-14, now in stage two trials. (Source: Bloomberg News, 26 March 2009)

Genentech Pulls Psoriasis Drug from US Market

The Genentech unit of drug maker Roche Holding AG is pulling the psoriasis treatment Raptiva from the US market because of links to an often fatal brain infection. The move comes only about six months after the company updated the drug's labeling to carry warnings of links to progressive multifocal leukoencephalopathy, or PML, a rare nervous system disorder. Genentech said it made the decision to pull the drug in conjunction with the FDA. Three cases of PML in Raptiva patients have been confirmed. One other patient on the drug developed similar neurological symptoms and died of an unknown cause.

Tysabri, a treatment for multiple sclerosis made by Biogen Idec, has also been linked to PML. Tysabri was pulled from the market in February 2005, and the company was allowed to resume selling the drug in July 2006. Since then, four new cases of PML have been reported in Tysabri users.

Genentech estimates about 2,000 people in the US are taking Raptiva and about 46,000 worldwide have taken it since its introduction in 2003. Raptiva accounted for \$108 million in sales in 2008 out of Genentech's total of \$13.42 billion. The drug was approved for chronic moderate to severe plaque psoriasis, a skin condition characterized by red, scaly, inflamed patches of skin.

Roche said its earnings won't be significantly affected by the decision, but it would take a \$125 million charge for supplies of the medicine made but not sold. Merck Serono, which has the license to distribute the drug outside the US and Japan, will alert other countries to the decision to pull the drug in the US, Genentech said. (Source: Associated Press, 9 April 2009)

J&J Eliminates 900 Sales Positions

Johnson & Johnson announced that it will eliminate approximately 900 sales reps in its Ortho-McNeil-Janssen division. The good news is that through attrition and hiring freezes the company was able to reduce the number of job losses. J&J is not providing the actual number of employees being eliminated; however, the 900 positions that were impacted represent approximately 6 percent of the total US Johnson & Johnson pharmaceuticals workforce. (Source: George Koroneos, Pharmexec, 15 April 2009)

Infinity Pharma Cancer Drug Trial Halted

Infinity Pharmaceuticals' lead cancer drug has failed in a late-stage clinical trial for treating relapsed forms of malignant stomach tumors, after interim results showed that more patients were dying when taking the drug than those who weren't on the drug, the company reports. The decision to halt the Phase 3 "RING" trial came after preliminary safety data showed that there was a higher mortality rate among the first 46 patients in the study who were treated with Infinity's drug. The drug is intended to knock out a tumor growth protein known as Hsp90. The company is telling clinical trial centers involved in the study to stop giving the drug to patients.

The firm is continuing separate trials using the drug to treat non-small cell lung cancer, metastatic breast cancer, and advanced solid tumors, but it plans to consult with other parties to decide if any changes are needed in those studies. "We continue to believe in the therapeutic potential of Hsp90 inhibition, and are committed to the development of both IPI-504 and our oral Hsp90 inhibitor, IPI-493," said Julian Adams, chief scientific officer of Infinity, in a statement.

The end of the RING trial follows London-based drug giant AstraZeneca's decision, revealed in December, to hand back to Infinity its 50 percent ownership stake in IPI-504, giving little reason for the decision and leaving Wall Street guessing. In May, Infinity reported that the drug could stabilize tumors for two-thirds of patients in a study of 36 patients, and keep tumors from spreading for about three months in patients who failed on all other treatments. The RING trial is said to have included a higher proportion of patients with more advanced tumors than the earlier study. (Source: Ryan McBride, Xconomy, 15 April 2009)

Glaxo Offers Patents to Aid Research

GlaxoSmithKline PLC will donate more than 800 of its patents to a pool that will be open to all researchers trying to develop medicines for neglected diseases, the company said, elaborating on an earlier pledge to do more for the developing world. The UK drug maker said it hopes other companies will also donate intellectual property to the pool, with the aim of speeding development of new drugs.

Glaxo released the details in its 2008 Corporate Responsibility Report. The company also pledged to publish a wider assortment of its drug studies than it has previously, in the aim of transparency. Drug companies including Glaxo have been accused in the past of suppressing negative results of some clinical trials.

Since 2004, Glaxo has posted on a Web site summaries of all clinical trials it has carried out on its marketed drugs. Now, Glaxo also will post to the site, which it set up specifically to relay drug-study information, all of the new metaanalyses it sponsors. Such studies analyze the results of multiple trials of the same drug to draw broader conclusions about safety and efficacy.

Glaxo also made new promises about disclosing its payments to doctors, a practice that has caused controversy for drug makers. For clinical trials starting in 2010 and beyond, Glaxo will publicly report the money it pays US doctors and their institutions to carry out the studies. Glaxo said it will start publishing clinical-trial payments to doctors outside of the US at a later date. Glaxo also said it would start reporting the fees it pays European doctors for advice on developing new drugs. That follows a promise Glaxo made last year to publish payments to US doctors for consulting and other services. (Source: R.I.C. Centre, 25 March 2009)

Synta Cancer Trial Failure has Major Downstream Effects

Synta Pharmaceuticals' decision to suspend its so-called Symmetry clinical trial procedures for its elesclomal drug candidate is having serious downstream effects, leading the company to postpone releasing its earnings report and to formulate a new strategy to compensate. In February, citing patient safety concerns, Synta announced it was

ending the Phase 3 study of its cancer treatment elesclomol. It also said it would suspend other ongoing studies with elesclomol, including one for prostate cancer, pending further analysis of the Symmetry trial results. Additionally, it said it would discuss future development of the drug with its partner, GlaxoSmithKline PLC, which earlier in February had made a payment of \$10 million to Synta, awarded for a melanoma-related operational milestone around elesclomol.

The suspension will seriously jeopardize the FDA's potential approval of elesclomol, according to one financial analyst. "While we handicap odds of approval for elesclomol at 10 percent, this may be optimistic," said Andrew Vaino, a senior research analyst at California-based investment bank Roth Capital Partners LLC. Previously, Vaino had said in a note published on Feb. 27, "Currently, all of Synta's value lies with elesclomol, in our opinion."

The suspended study's intent was to compare elesclomol in combination with the established cancer drug paclitaxel to paclitaxel alone in patients with stage 4 metastatic melanoma who had never had chemotherapy. However, an independent monitoring committee found that there had been an "imbalance in overall survival" in the patients - that is, there had been more deaths occurring in the patients taking elesclomol with paclitaxel, than compared to those taking paclitaxel alone.

Despite the setbacks, Synta has tried to sound a positive note. The company issued a statement via email that pointed out the elesclomol Phase 3 melanoma study "was only one of many interesting programs at the company." Synta claimed to have a strong balance sheet, two years of operating capital and a strong pipeline with five publicly disclosed programs. It is "absolutely our intent to continue to develop our drug candidates," the company stated. (Source: Marc Songini, Mass High Tech, 13 March 2009)

Proteon Raises \$38 Million, Signs Deal with Novartis

Proteon Therapeutics Inc., a privately held Waltham biopharmaceutical company, said that it has completed a \$38 million Series B equity financing led by MPM Capital, a firm with Boston offices that invests in life sciences companies. Proteon said it has also entered an agreement with Novartis that grants the Swiss drug maker an exclusive option to acquire Proteon following the "successful completion of a Phase 2 clinical study of PRT-201 with a potential secondary right to a global license under pre-agreed conditions. Including the initial acquisition payment plus potential additional regulatory milestone payments, the deal with Novartis could exceed \$550 million," Proteon said.

Proteon's drug candidate, PRT-201, aims to improve vascular access in patients currently on or being prepared for hemodialysis. In September, the company said that PRT-201 had received fast-track designation from the FDA. The FDA's fast-track designation is intended to facilitate development and expedite review for drugs that treat serious diseases and fill unmet medical needs. (Source: Chris Reidy, The Boston Globe, 5 March 2009)

Genzyme Acquires Rights to Cancer Drug Campath

Genzyme, the Cambridge biotech giant best known for targeting rare genetic disorders like Pompe disease and Fabry disease, is increasing its investment in drugs to treat broader diseases such as cancer and multiple sclerosis. The company said it struck a multimillion dollar deal with Bayer HealthCare to acquire most of Bayer's rights to Campath, a cancer drug in advanced clinical trials to treat multiple sclerosis. Genzyme acquired Campath when it bought llex Oncology Inc. of San Antonio in 2004 but shares marketing and distribution rights with Bayer HealthCare, a subsidiary of Bayer AG of Germany.

In addition, Genzyme is buying two established cancer drugs from Bayer, Fludara and Leukine. As part of the deal, next year Genzyme will buy Bayer's manufacturing plant near Seattle - where Leukine is produced - for \$75 to \$100 million. Instead of buying the drugs upfront, Genzyme agreed to make gradual payments based on how well the treatments sell. If they generate enough revenue, the deal could ultimately be worth \$2.9 billion, including the price of the plant, over the next 11 years. Much of the money is contingent on Campath's approval by the FDA to treat multiple sclerosis, a chronic disease that interrupts the flow of information to the brain and causes symptoms that range from numbness to paralysis. The company hopes to win FDA approval in 2012.

J.P. Morgan analyst Geoffrey Meacham, who has a "neutral" rating on Genzyme's stock, had a mixed reaction to the Bayer news. "Our take is that the deal makes strategic sense as Campath MS is an important pipeline asset for Genzyme," Meacham wrote in a note to investors. "However, we question why Bayer is a willing seller if it shares Genzyme's enthusiasm. Regardless, he noted that Genzyme has already made a major investment in Campath to treat multiple sclerosis and has highlighted the drug at a meeting with investors. If approved for multiple sclerosis, it could potentially compete with some drugs made by Biogen Idec.

In addition, Genzyme said the deal will provide an immediate boost to its cancer treatment franchise. The company estimated it would increase oncology revenue by \$185 million this year and up to \$700 million over the next three years. Last year, the oncology segment accounted for \$117 million in sales. Genzyme said the deal will help it meet its goal of increasing earnings by 20 percent a year from 2006 to 2011. (Source: Todd Wallack, The Boston Globe, 1 April 2009)

AVEO Pharmaceuticals and Biogen Idec Forge Alliance

Cambridge-based AVEO Pharmaceuticals has entered a strategic alliance with Biogen Idec to develop and commercialize potential treatments for cancer and other diseases. While the agreement entitles AVEO to an upfront payment as well as milestone payments if certain conditions are met, the financial details of the transaction were not disclosed.

Also, Biogen Idec may have found a treatment for the deadly brain infection that has been tied to use of its multiple sclerosis drug Tysabri, the biotechnology company's fastest-growing product. A malaria pill developed during the Vietnam War is being tested by Biogen on patients with progressive multifocal leukoencephalopathy, the brain disorder known as PML. Tysabri was pulled from the market in 2005 after three PML cases were reported. It was reintroduced a year later when US regulators said the medication's effectiveness, twice that of other MS drugs, outweighed its risks. (Source: The Boston Globe, 25 March 2009)

Pfizer Outlines R&D Structure After Merger with Wyeth

Because Pfizer wants to hit the ground running when it completes its acquisition of Wyeth this year, it has already announced the structure that its substantial R&D operation will take. Building on the complementary strengths of the companies, Pfizer will form two research organizations supporting the combined company's nine business areas.

Instead of having a single R&D unit spending its more-than-\$10 billion annual research budget, the company will divide efforts into two distinct groups led by presidents reporting directly to CEO Jeffrey B. Kindler. Pfizer's current global R&D head, Martin Mackay, will lead PharmaTherapeutics Research Group, which is focused on small molecules. BioTherapeutics Research Group will concentrate on large molecules and vaccines under the direction of Wyeth's current research president, Mikael Dolsten. It also will incorporate Pfizer's entrepreneurial Biotherapeutics & Bioinnovation Center, headed by Corey Goodman. "Creating two distinct, but complementary, research organizations, led by the top scientist from each company, will provide sharper focus, less bureaucracy, and clearer accountability in drug discovery," Kindler said when announcing the new structure.

After its previous acquisitions of Warner-Lambert and Pharmacia, Pfizer was criticized for moving too slowly and stalling innovation; Kindler admitted as much when the Wyeth deal was announced. Planning ahead this time, Pfizer expects its combined R&D operation will be positioned to start immediately after the merger is completed.

Still, Martha Freitag, a stock analyst at Argus Research, recently warned clients that there will be definite challenges in successfully integrating the two large companies. The combination is expected to accelerate already-planned job cuts and cost-saving moves. In 2008, both companies had begun reorganizing their R&D operations, exiting research in certain disease areas and concentrating more closely on others.

Within the two new R&D groups, Pfizer will create smaller, focused teams targeting specific therapeutic areas and headed by chief scientific officers pulled from both Pfizer and Wyeth. Another team of scientists will seek and evaluate new technologies and early-stage drug candidates from outside Pfizer. (Source: Ann Thayer, Chemical & Engineering News, 13 April 2009)

Some Local Life Sciences Companies Expand while Others Cut Back

Despite the global credit crunch, a handful of large Bay State life sciences companies say they are continuing to expand. Vertex Pharmaceuticals, which is gearing up to market a highly anticipated drug to treat hepatitis C, plans to hire 200 to 300 new employees this year in Massachusetts. The company currently has at least 1,300 employees, including more than 1,000 at its Cambridge headquarters.

Genzyme chief executive, Henri A. Termeer, said the Cambridge biotechnology giant plans to add 300 to 400 jobs this year, mostly in manufacturing, as demand continues to increase for its drugs. But in past years, Genzyme grew even faster. It has 11,200 employees, including nearly 4,500 in Massachusetts. "This is a very healthy industry, but we have an interruption," Termeer said. "It is important to understand that we are not immune" to the recession.

Millennium Pharmaceuticals, a unit of Japan's Takeda Pharmaceutical Co. that focuses on developing cancer drugs, plans to add 100 to 150 positions this year; it currently has 1,300 employees, mostly in Cambridge. And EMD Serono, the Rockland-based affiliate of German drug maker Merck KGaA, has announced plans to open a Cambridge research facility with 50 scientists. The company now has 800 employees in the state.

At the same time, many local companies are cutting back. The financial crisis has wreaked havoc with some smaller life sciences companies that still need to raise money as they seek to develop drugs, medical devices, or other products. More than a dozen life sciences companies, including Oscient Pharmaceuticals in Waltham and Acusphere in Watertown, have slashed their workforces in recent months to conserve cash. And some are folding altogether, including Codon Devices in Cambridge.

Pearl Freier, a Cambridge headhunter for the life sciences industry, said some companies are continuing to fill key jobs. But it's not enough to offset the legions of firms that are slashing payrolls, she said. "There are companies every week that are going under," said Freier, president of Cambridge BioPartners Inc. "It's a difficult time. I am flooded with candidates."

Many companies with products already on the market have done better. Termeer predicted Genzyme's sales will continue to show double-digit growth this year. And some, like Vertex, have been able to continue to raise money because they are relatively close to winning federal approval for drugs with enormous potential.

A number of firms are holding steady. Millipore, a Billerica company that makes equipment for the life sciences industry, said its employment will likely be flat or shrink slightly in Massachusetts. However, it's moving a manufacturing operation from Northern California to Danvers. The company has 5,900 employees, including 1,100 in Massachusetts. "We see Massachusetts as a key site for us," said Millipore's chief executive, Martin Madaus. "We have a big research organization, and we plan to do more."

Thermo Fisher Scientific, which sells laboratory equipment, said its Bay State employment is "expected to remain relatively stable" this year. The Waltham firm currently has 1,500 employees in the state. And Covidien in Mansfield, which makes medical devices and other health products, doesn't anticipate any major changes in employment in Massachusetts this year, said a spokesman.

Charles River Laboratories, the Wilmington company that breeds mice and rats for researchers, recently cut 3 percent of its workforce, including 50 jobs in Massachusetts, because of softer demand from drug companies. Even so, chief executive James Foster said the company plans to gradually expand, including doubling the size of its new Shrewsbury facility in the next three to five years and adding people at its headquarters. The company currently has 420 employees in Shrewsbury and 850 in Wilmington. (Source: Todd Wallack, The Boston Globe, 14 April 2009)

GlaxoSmithKline and Pfizer to Create New HIV Company

GlaxoSmithKline and Pfizer announced they have entered into an agreement to create a new, world-leading HIV company focused solely on research, development and commercialization of HIV medicines. The new HIV business will be more sustainable and broader in scope than either company's individually, and will hold a 19 percent share of the growing market and have an industry-leading pipeline. GSK will initially hold an 85 percent equity interest in the new company and Pfizer will hold 15 percent.

The new company will have a broad product portfolio of 11 marketed products including market-leading therapies

such as Combivir, Kivexa and Selzentry/Celsentri and an industry-leading pipeline of 6 innovative and targeted medicines, including four compounds in Phase 2 development. Altogether, the new company will have 17 molecules at its disposal to develop in fixed-dose combinations as possible new HIV treatments. The new company will contract R&D services directly from GSK and Pfizer to develop these medicines.

The new company will also invest in early-stage research and discovery of HIV medicines, and will benefit from a new Research Alliance Agreement with GSK and Pfizer. Under this new alliance, GSK and Pfizer will continue to conduct discovery research and development into HIV medicines and the new company will invest in this activity and will have exclusive rights of first negotiation in relation to any new HIV-related medicine developed by either GSK or Pfizer.

Not-for-profit pricing for HIV medicines will continue for those countries most in need, and the new company will continue to facilitate new voluntary licenses to diversify production and expand capacity in these markets. The new company will also conduct research and development activities specifically to address appropriate access to HIV medicines in developing countries. In particular, the new company will increase its research effort into treatments and formulations for children living with HIV.

The new company will continue GSK and Pfizer's strong record of community support for HIV. GSK's long-standing Positive Action program will transfer to the new company, maintaining a focus on prevention, tackling stigma and discrimination, and building capacity and treatment literacy within the global community (Source: GlaxoSmithKline, 16 April 2009)

Alnylam and Isis Form Collaboration on ssRNAi

Alnylam Pharmaceuticals and Isis Pharmaceuticals have formed a collaboration focused on the development of single-stranded RNAi (ssRNAi) technology. The alliance gives Cambridge-based Alnylam access to Isis's intellectual property and expertise regarding ssRNAi antisense drugs. Both firms will have the opportunity to discover and develop drugs employing the new technology. California-based Isis and Alnylam also agreed to extend their broad cross-licensing arrangement regarding double-stranded RNAi, which was established in 2004.

RNA interference is a naturally occurring mechanism within cells for selectively silencing and regulating specific genes. Since many diseases are caused by the inappropriate activity of specific cells, the ability to silence genes selectively through RNAi is thought to have great potential. Alnylam will potentially pay Isis up to \$31 million in license fees, a press release said. (Source: Chris Reidy, The Boston Globe, 30 April, 2009)

Massachusetts Life Sciences Companies get \$3.4 Million in State Loans

Seven early-stage life sciences companies have been awarded a total of \$3.4 million in loans under the state's \$1 billion life sciences initiative. The so-called Accelerator loans were approved by the Massachusetts Life Sciences Center, a quasi-public agency charged with implementing the state's life sciences program. The center received 88 applications for the loans.

Winning loans of up to \$500,000 were Eutropics Pharmaceuticals of Boston, an oncology drug company; Good Start Genetics of Boston, a molecular diagnostics company; InVivo Therapeutics of Cambridge, a stem cell and biomaterials company; Pluromed of Woburn, a maker of injectable plugs for surgery; Spectra Analysis of Marlborough, a supplier of spectroscopy systems; Wadsworth Technologies of Westborough, a medical device company; and Wolfe Laboratories of Watertown, a pre-clinical services firm.

A major goal of the loan program is to boost companies in the critical stage between when they license medical technology and the time they can attract venture capital or other financing. Another goal is to help companies expand in Massachusetts. Applicants were evaluated by the life sciences center's advisory board, chaired by Harvey Lodish, biology professor at the Massachusetts Institute of Technology.

Since the 10-year, \$1 billion life sciences initiative was signed into law by Governor Patrick last July, the center has invested \$42.5 million - some of it previously appropriated - in projects, organizations, and researchers. But the amount set aside for loans and other investments in the current fiscal year was reduced 40 percent, from \$25 million to \$15 million, by the Legislature in January. In an interview, Patrick said he hoped to increase annual funding as the economy strengthens. (Source: Robert Weissman, The Boston Globe, 30 April, 2009)

Vertex Drug Shows Promise Against Hepatitis C

According to results of midstage testing published in the New England Journal of Medicine, an experimental drug greatly increased the number of people who appear to be cured of hepatitis C infection. The findings also suggest that the drug, telaprevir, made by Vertex Pharmaceuticals, which sponsored the two studies, can cut treatment time from one year to six months. However, those taking the drug reported more side effects, including severe rash, nausea, and anemia, than those on standard treatment alone.

Still, telaprevir and similar drugs that other companies are testing offer hope of a major advance against the disease, which afflicts about 3.2 million Americans and 180 million people worldwide. It is caused by a bloodborne virus that can lead to liver scarring or liver cancer.

Treatment is aimed at helping the immune system eliminate the virus. Current therapy combines the drugs peginterferon and ribavirin, but fewer than half of the patients on them are cured. Telaprevir and similar drugs under development are a potential game-changer because they specifically attack the hepatitis C virus. In the two studies, roughly two-thirds given telaprevir with standard therapy for six months showed no signs of the virus after six months, which doctors considered being cured of the disease, compared to 40 to 50 percent on standard treatment alone. Telaprevir is in late-stage testing and is not available commercially; Vertex plans to seek government approval next year.

Hepatitis C is a huge and growing problem because for years there was no way to screen the blood supply for the virus. Infection often doesn't produce symptoms for many years, so many of these cases are just now being recognized, even though they may stem from transfusions a decade or more ago.

The virus is mainly spread through contact with the blood of an infected person. About one-quarter of people exposed to hepatitis C clear it out of their bodies without treatment. But the rest develop a lifelong infection that

attacks their livers. There is no vaccine to prevent hepatitus C infection. (Source: Alicia Chang, Associated Press, as reported in The Boston Globe, 30 April 2009)

GTC Therapeutics ATryn Available for Patients with Rare Blood Clotting Disorder

Lundbeck, Inc has announced that ATryn is now available in the US. In February 2009, the FDA granted marketing approval of ATryn, developed through recombinant technology, for the prevention of peri-operative and peri-partum thromboembolic events in patients with hereditary antithrombin deficiency (HD AT), a rare and potentially fatal blood clotting disorder. The product is marketed in the US by Lundbeck Inc. and manufactured by GTC Biotherapeutics.

Antithrombin is a naturally occurring protein that helps regulate the blood clotting mechanism in the body. People with hereditary antithrombin deficiency have lower than normal levels of antithrombin, putting them at increased risk for venous thromboembolic events (VTEs), including pulmonary embolism and deep vein thrombosis, which can be life threatening, particularly in the high-risk situations of surgery or childbirth. Prior to the availability of ATryn, HD AT patients undergoing surgery or giving birth requiring an antithrombin therapy relied on a human plasma derived product. Approximately one in 2,000 to one in 5,000 people have hereditary antithrombin deficiency. By the age of 50, approximately 50 percent of people with hereditary antithrombin deficiency will have experienced a VTE.

Developed and manufactured by GTC Biotherapeutics, ATryn was created to provide a safe and reliable supply of recombinant antithrombin. ATryn is made by processing the human antithrombin protein from the milk of a select herd of transgenic goats. The process for producing ATryn involves scientists inserting DNA for the human antithrombin protein into a single-celled goat embryo. This embryo is implanted into a surrogate doe. The resulting transgenic offspring are able to produce high levels of human antithrombin in their milk. This protein is collected and purified from the milk to produce ATryn, which is administered to patients by intravenous infusion. (Source: Lundbeck Inc. Website, 6 May, 2009)

Regulatory & Legislative Highlights

by Deepen Joshi, Sepracor, Inc.

FDA to Collaborate with Academic and Research Institutions under Nanotechnology Initiative

The FDA unveiled a new collaboration initiative with the Houston-based Alliance for NanoHealth (ANH) and its eight member institutions to help speed development of safe and effective medical products in the emerging field of nanotechnology. The FDA/ANH Nanotechnology Initiative will work to expand knowledge of how nanoparticles behave and affect biologic systems, and to facilitate the development of tests and processes that might mitigate the risks associated with nanoengineered products. All outcomes from this public-private partnership will be placed in the public domain for the benefit of all stakeholders.

Nanotechnology involves the creation and use of materials at the level of molecules and atoms and presents challenges and opportunities for the FDA's entire regulatory product jurisdiction, from food to medical devices to therapeutics. The eight academic institutions include Baylor College of Medicine, the University of Texas' M.D. Anderson Cancer Center, Rice University, the University of Houston, the University of Texas Health Science Center at Houston, Texas A & M Health Science Center, the University of Texas Medical Branch at Galveston, and the Methodist Hospital Research Institute. (Source: FDA Website, 10 March, 2009)

FDA Approves First DNA Test for Two Types of Human Papillomavirus

The FDA has approved the first DNA test that identifies the two types of human papillomavirus (HPV) that cause the majority of cervical cancers among women in the United States. The test, called Cervista HPV 16/18, detects the DNA sequences for HPV type 16 and HPV type 18 in cervical cells. Differentiating these HPV types gives health care professionals more information on a patient's risk of subsequently developing cervical cancer. A positive Cervista 16/18 test result indicates whether HPV type 16, 18 or both types are present in the cervical sample.

The FDA also approved the Cervista HPV HR test, which is the second DNA test that detects essentially all of the high-risk HPV types in cervical cell samples. The Cervista HPV HR test uses a method similar to the Cervista HPV 16/18 test to detect the DNA sequences of these HPV types. In women age 30 and older or women with borderline cytology, the Cervista HPV 16/18 test can be used together with cytology and the Cervista HPV HR test to assess risk of cervical disease.

HPV is the most common sexually transmitted infection in the US. The Centers for Disease Control and Prevention estimates that more than 6 million Americans become infected with genital HPV each year and that more than half of all sexually active women and men become infected at some time in their lives. Cervista HPV 16/18 and Cervista HPV HR are manufactured by Third Wave Technologies of Madison, Wisconsin. (Source: FDA Website, 13 March, 2009)

FDA Approves Drug for Advanced Form of Kidney Cancer

The FDA has approved Afinitor oral tablets (everolimus) for the treatment of patients with advanced kidney cancer whose disease has progressed after treatment with other cancer therapies.

Renal cell cancer, the most common type of kidney cancer, originates in the lining of the small tubules in the kidney that filter waste products from the blood. The cancer is resistant to such standard treatments as radiation therapy and chemotherapy, and the initial treatment for most patients is surgical removal of the kidney. If the cancer is confined to the kidney, the five-year survival rate is 60 to 70 percent; but the survival rate is considerably lower after the cancer has spread to other parts of the body.

Afinitor belongs to a class of drugs called kinase inhibitors, which interfere with cell communication, preventing tumor growth. The drug is intended for those patients with advanced renal cell cancer who have already tried another kinase inhibitor, Sutent (sunitinib) or Nexavar (sorafenib).While Sutent and Nexavar are multiple kinase inhibitors (acting on a number of cellular targets), Afinitor works by blocking a specific protein known as the mammalian target of rapamycin or mTOR. The protein blocking action disrupts the growth, division and metabolism

of cancer cells.

Afinitor is manufactured by Novartis International AG of Basel, Switzerland; Sutent is manufactured by Pfizer Inc. of New York; and Nexavar is manufactured by Bayer HealthCare AG, Leverkusen, Germany. (Source: FDA Website, 30 March, 2009)

FDA Clears Rapid Test for Avian Influenza A Virus in Humans

The FDA has approved a new, more rapid test for the detection of influenza A/H5N1, a disease-causing subtype of the avian influenza A virus that can infect humans. The test, called AVantage A/H5N1 Flu Test, detects influenza A/H5N1 in throat or nose swabs collected from patients who have flu-like symptoms. The test identifies in less than 40 minutes a specific protein (NS1) that indicates the presence of the influenza A/H5N1 virus subtype. Previous tests cleared by the FDA to detect this influenza A virus subtype can take three or four hours to produce results.

Influenza A infects both humans and animals. H5N1 is a subtype that is found mostly in birds, although infections have also occurred in humans, mostly in people who have come into contact with the virus through infected poultry. According to the Centers for Disease Control and Prevention, of the few avian influenza viruses that have infected humans, the H5N1 subtype has caused the largest number of detected cases of serious disease and death. AVantage A/H5N1 Flu Test is manufactured by Arbor Vita Corporation, located in Sunnyvale, Calif. (Source: FDA Website, 7 April, 2009)

FDA Approves Coartem Tablets to Treat Malaria

The FDA has approved Coartem tablets (artemether and lumefantrine) for the treatment of acute, uncomplicated malaria infections in adults and children weighing at least 11 pounds. Coartem is not approved for the treatment of severe malaria nor to prevent malaria. Severe malaria is different than acute, uncomplicated malaria in that patients with severe malaria have altered consciousness and other metabolic and end-organ complications. These patients are not candidates for oral drugs and should be given intravenous anti-malarial therapy.

Coartem is made by Novartis Pharmaceuticals Corporation, Basel, Switzerland.

In compliance with a provision of the FDA Amendments Act of 2007, the FDA awarded Novartis a one-time priority review voucher to use towards a future new drug application. The provision, which was designed to encourage development of drugs to treat tropical diseases, authorizes the granting of such vouchers to sponsors of treatments for certain tropical diseases. The voucher may be transferred by the recipient to another manufacturer. (Source: FDA Website, 8 April, 2009)

FDA to Review Medical Devices Marketed Prior to 1976

The FDA has announced that manufacturers of 25 types of medical devices marketed prior to 1976 must submit safety and effectiveness information to the agency so that it may evaluate the risk level for each device type. Devices found by the FDA to be of high risk to consumers will be required to undergo the agency's most stringent premarket review process.

These 25 device types, which are listed in the Federal Register, were marketed in the US prior to the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1976. That law authorized the FDA to review new medical devices.

The FDA classifies medical devices into three categories according to their level of risk. Class III devices represent the highest level of risk and generally require a showing of safety and effectiveness before they may be marketed. Class III devices include heart valves and intraocular lenses. Class I and Class II devices pose lower risks and include devices such as adhesive bandages and wheelchairs.

Manufacturers of the 25 remaining device types must submit the requested information within 120 days. The FDA will review the submitted data and, based on the risk level, issue regulations for each device type that either will require manufacturers to submit premarket approval applications or will re-classify the devices into Class I or Class II.

(Source: FDA Website, 8 April, 2009)

FDA Approves Drug for Three Types of Immune-Related Arthritis

The FDA has approved Simponi (golimumab), a monthly treatment for adults with moderate-to-severe rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis. All three conditions are chronic disorders in which the immune system attacks multiple joints, causing stiffness, pain, and restricted motion.

Simponi is injected under the skin. It is intended for use in combination with the immunosuppressant drug methotrexate in patients with rheumatoid arthritis. It also may be used with or without methotrexate for psoriatic arthritis and alone in patients with ankylosing spondylitis, a chronic inflammatory arthritis of the spine.

Simponi is in a class of drugs that target and neutralize tumor necrosis factor-alpha (TNF-a), a protein that, when overproduced in the body due to chronic inflammatory diseases, can cause inflammation and damage to bones, cartilage and tissue. The FDA required a risk evaluation mitigation strategy (REMS) for Simponi, as it required for other TNF-a blockers. The REMS for Simponi includes a Medication Guide for patients and a communication plan to help prescribers understand the drug's risks. Simponi is marketed by Centocor Ortho Biotech Inc., Malvern, Pa. (Source: FDA Website, 24 April, 2009)

Draft Rules Expand Stem Cell Research Options

The federal government has released its draft rules for funding embryonic stem cell research - expanding opportunities but stopping short of allowing government-sponsored scientific projects to use human embryos created solely for experimental purposes.

The NIH proposed limiting federally funded research to use of embryos that would otherwise be discarded from fertility clinics. That is expected to significantly expand the number of stem cell lines available to researchers who seek to do basic research and develop treatments for a variety of intractable diseases. The Obama administration

made clear it does not intend to finance research that uses embryos created solely for research purposes or cloned by scientists - more controversial procedures with less public and congressional support.

Some researchers are concerned that the funding guidelines, which require that embryo donors be informed of their options and consent in writing to their scientific use, would exclude stem cells that are currently in use, because it may no longer be possible to identify their donors. Human embryonic stem cells have been largely separated from information to maintain donors' privacy.

In response to public pressure to seek better treatments for illnesses including cancer and Alzheimer's disease, Congress has twice passed laws to approve federal funding for stem cell research that uses human embryos from fertility clinics. On both occasions, President Bush vetoed the legislation. (Source: Bina Venkataraman, The Boston Globe,18 April, 2009)

FDA Cites Misleading Drug Ads on Web

Biogen Idec, Pfizer, Sanofi-Aventis and 11 other drug makers were cited by US regulators for "misleading" ads on Internet search engines. The FDA faulted the 14 companies for failing to identify product names and side effects associated with the drugs in sponsored search results, according to information posted on the agency's website. The FDA sent letters ordering the companies to halt the ads.

Companies and interest groups pay search engine operators such as Google to post links to their websites in a sidebar after someone types in a related search term. With drug makers, the sponsored links usually include a headline and short blurb about the relevant medical condition or product.

Other companies to receive letters were Cephalon, Merck, Roche, Bayer, Johnson & Johnson, Forest Laboratories, Eli Lilly, Boehringer Ingelheim, Genentech, GlaxoSmithKline and Novartis. (Source: The Boston Globe, 4 April, 2009)

New Members

Larry Backus, Specialist - Vacuum Technology, L.A. BACKUS & Associates, Inc

Fulden Buyukozturk, Student, Northeastern University

Ms. Judy Carmody, President, AVATAR Pharmaceutical Services, Inc.

Mr. Joe Donovan, Biopharmaceutical Sales Manager, Bioquell Inc.

Ms. Marsha R. D'Souza, Student, Northeastern University

Dr. Thomas M. Eckrich, Head, Res/Dev, Eli Lilly and Company

Mr. Daryl Flynn, President, Plastic Design, Inc.

Vikas Gupta, Group Product Manager, Millipore Corporation

Mr. Nathan A. Hickey, Regional Factory Representative, Feldmeier Equipment Inc

Vishnu Hosur, M.S., Graduate Student, Northeastern University

Mr. Kris lyer, Controls Engineer, Organogenesis

Mrs. Lara S. Jabr, PhD Student, Northeastern University

Mr. Ryan E. Jarvis, Life Science Business Manager, Sensitech

Jeffrey D. Kent, , Queens University

Mr. Geoffrey M. Kuesters, PhD Candidate, Northeastern University

Ms. Christina A. Ostermier, Architectural Designer/Drafter, Parsons, Inc.

Mr. Albert J. Porras, Program Manager, NSTAR

Mr. James M. Scearbo, Engineer, Avecia Biotechnology

Mr. Aalok A. Shah, Master of Science, Northeastern University

Mr. Gowda Shrikanth, Applications Engineer, Millipore Corporation

Mr. David J. Standring, Jr., Senior Manufacturing Engineer, Siemens Healthcare Diagnostics

Ms. Ayni N. Strang, Senior Manager, Facilities, Acceleron Pharma, Inc.

Wasim Syed, Sr Computer Validation Engineer, Shire Pharmaceuticals

Yuanyuan Tao, Student, Worcester Polytechnic Institute

Matthew Teli, ,

Mr. Paul A. Ullucci, Laboratory Director, ESA Laboratories, Inc.

<u>Back</u>

Chapter Manager: Amy Poole, CAMI - Tel: 1.781.647.4773 and E-mail: ispe@camihq.com

Powered By <u>NMDeluxe</u> with enhancements by <u>Ashdown Technologies, Inc.</u>