



Vienna Life Sciences explore China (Part1)

“Surprisingly Ingenious” was the slogan when Vienna biotech companies visited China. From the 20th to the 26th of May, a delegation of Austrian enterprises – headed by the president of the Vienna Economic Chamber, Brigitte Jank – travelled to Beijing, Suzhou and Shanghai.

With 1.3 billion people, China represents significant opportunity for both multinational and domestic drug companies. As of 2011, China has become the second largest pharmaceutical market worldwide and is expected to continue its rapid growth to overtake the US as the largest market by 2020. This rapid growth can be attributed to the increasing demand within China, driven by factors such as the rapidly aging population and the increasing incidence of chronic diseases. The overall aging trend within the Chinese population creates an increasing demand for pharmaceuticals. This is also related to the increasing incidence of chronic diseases. Annually, 80% of all disease-related deaths in China are a result of chronic disease such as cardiovascular disease, stroke and cancer.

While historically China's pharmaceutical industry has focused on the generics mar-

ket, China's current demand has shifted its focus towards novel drug development. As the pharmaceutical industry seeks to meet the healthcare needs of China's population through increased pharmaceutical development, there are a growing number of clinical trials being performed within China. In 2009, over 1,000 clinical trial protocol applications were approved by the SFDA. A significant number of these had international applications as part of multinational trials, demonstrating China's increasing ability to develop drugs for both the Chinese and global market.

A further demonstration of the increasing number of Chinese clinical trials can be seen in the growing number of trials in China sponsored by multinational companies. Prior to 2003, there were less than 20 trials sponsored by multinational companies initiated per year, and this number jumped to 129 trials in 2010. This increasing interest in developing pharmaceuticals for the Chinese market has led to the establishment of a number of certified clinical trial institutions. There are over 320 certified institutions, ranging from state-run hospitals to specialized clinics. They are spread all over the 31 different provinces but are mainly located in the life science hubs

such as Beijing, Shanghai and Guangdong. Pharmaceutical developers benefit from the relatively low cost of clinical trials in China. This cost efficiency is in part due to the ease of patient recruitment in China. Delays in patient recruitment are a bottleneck for pharmaceutical development and can cost up to \$ 35,000/day. By contrast, patient enrolment time in China can be reduced by as much as 30% compared to Western countries.

China's diverse disease burden results in a large unmet medical need that drives its pharmaceutical industry to develop therapeutics specifically addressing the medical problems of the Chinese population. There is an emphasis on oncology and infectious disease such as viral hepatitis. This focus demonstrates that developers in China are primarily focused on developing drugs for China, while international applications for Chinese drugs are increasing. The many benefits of performing clinical trials in China only serve to increase the attractiveness of the Chinese market. (continue page 3)





Dear Readers

Over the last few months, LISAvienna has offered a number of international marketing activities to support business for the Austrian life science industry.

LISAvienna organised for its members a one-week experience ("Zukunftsreise") to the Chinese life science industry. From May 20th to 26th, around 15 Austrian biotechnology companies visited China. The Austrian Embassy in Beijing and the Austrian Consulate General in Shanghai arranged a one-week trip from Beijing to Suzhou and Shanghai. The agenda included interesting introductions, visits and meetings in Chinese biotech companies, B2B meetings for the Austrian delegates with Chinese companies in Beijing and Shanghai, as well as the two-day ChinaBio Partnering Forum in Suzhou. We would like to thank all the participating companies who made this trip successful as well as the Vienna Chamber of Commerce and Advantage Austria for the excellent partnership.

Austrian biotech companies also joined LISAvienna on June 18–21, 2012 at the BIO International Convention in Boston, the largest global event for the biotechnology industry, which is attended by around 15,000 biotech specialists. The convention attracts the biggest names in biotech, offers key networking and partnering opportunities, and provides insights and inspiration regarding the major trends affecting the industry. LISAvienna attended this conference with the Advantage Austria pavilion and used the opportunity to demonstrate Austrian innovative biotech enterprises and to establish and maintain international business contacts. A highlight this year was Life Science Austria's networking invitation to the MIT Faculty Club. About 100 companies attended this event to listen to the experience of biotech entrepreneur Hans Loibner (Apeiron Biologics) and Tillman Gerngross (Adimab).

LISAvienna celebrates its 10th anniversary on September 13, 2012 and we invite you to celebrate with us the successes of the Vienna Life Science Cluster! Many distinguished guests are expected, among them Renate Brauner, MA, Deputy Major of Vienna; Prof. Dr. Hartmut Ehrlich, Vice President of Global R&D and Medical Affairs, Baxter; Dr. Sonja Hammerschmid, Rector of the Veterinary University of Vienna and Co-founder of LISAvienna; and many more! Be sure to save the date!

Peter Halwachs and Johannes Sarx

LISAvienna Executive Board

What we offer

- :: Consulting
- :: Marketing
- :: Qualification
- :: Networking
- :: Knowledge

LISAvienna (Life Science Austria Vienna) is your key professional partner in Vienna when it comes to biotechnology/pharmaceuticals and medical technology. Whether you are an entrepreneur, an investor or a researcher, LISAvienna provides you with essential services in Austria's largest life science location.

For more information please visit our website: www.LISAvienna.at



Meet LISAvienna abroad

1. World Medtech Forum 2012
Luzern, September 25-27, 2012

BIO-Europe
Hamburg, November 12-14, 2012

Medica
Düsseldorf, November 14-17, 2012

Life Science Events in Vienna *

ENEA 2012
www.enea2012.org
September 12–15, 2012, Hofburg, Vienna

ESMO
www.esmo.org/events/vienna-2012-congress.html
September 28, 2012 – October 2, 2012,

Biomarker Development 2012
www.biomarker-development.com
October 3–4, 2012, Tech Gate Vienna

ECNP Congress
www.ecnp.eu
October 13–17, 2012, Austria Center, Vienna

*) This list is not exhaustive – for more information, visit our homepage: www.LISAvienna.at

LISAvienna Events **

10th Anniversary of LISAvienna
www.LISAvienna.at
September 13, 2012, Rinderhalle Neu Marx (Media Opera), Vienna

LISAvienna Business Seminar
Strategy planning in medical product development: from clinical investigation and assessment to health technology assessment and reimbursement
September 20, 2012, aws, Vienna

LISAvienna Business Treff
Visit of the Viennese life science enterprise Biomedica and hear also about Braincon and their joint venture DCX Technologies
October 24, 2012, Biomedica, Vienna

***) Our events are free of charge. For registration please visit our website www.LISAvienna.at

Vienna Life Sciences explore China (Part 2)

The trip to China took just five days in May 2012. Brigitte Jank, president of the Vienna Economic Chamber, and the 14 participating Austrian biotech companies used this opportunity for an intensive round of consultations with politicians, academics and companies.

(continue page 1) In addition to the growing industry expenditure on R&D, the Chinese government has made the development of the biotechnology sector a priority in their 12th five-year plan (2011–2015) by dedicating \$ 3.1 billion to its continued development. The increased industry and government expenditure on R&D has already resulted in the development of novel therapeutics with a total of 3,200 novel molecule patents published since 2000. While not all will qualify for the special IND application for innovative drugs, this increasing focus on developing novel drugs for the Chinese market is evidence of growing drug development within China.

In contrast to novel drug development are the recent changes in China's patent law in a fight for cheaper drugs. In May 2012, Chinese intellectual property laws were overhauled to allow the nation's drug makers to make less expensive copies of medicines that will still be under patent protection. The move by China, considered a vital growth market for foreign pharmaceutical companies, comes within months of a similar move by India to effectively end the monopoly on an expensive cancer drug made by Bayer AG by issuing its first so-called "compulsory licence."

The amended patent law allows Beijing to issue compulsory licences to eligible companies to produce generic versions of patented

drugs during state emergencies, unusual circumstances, or in the interest of the public. For "reasons of public health," eligible drug makers can also ask to export these medicines to other countries, including members of the World Trade Organisation. Topics were the fields of pharmaceutical research, medical devices and biotechnology, which are areas China invests in heavily. Austria is located in the heart of Europe and is regarded as a bridge between Eastern and South-eastern Europe. One main focus of the trip was the presentation of the life science cluster in Vienna.

In Shanghai, Vienna Economic Chamber entered a bilateral agreement for technological cooperation with the industry organisation Saitech. The delegates of the trade mission to China represented the entire range of the life science industry in Vienna: scientists from the Vienna General Hospital (AKH), pharmaceutical companies with new products for the Chinese market, a manufacturer of medical devices, production manufacturers of pharmaceuticals, and a service company for clinical trials were all looking for partners in China.

Johanna Uhlmann of Vienna-based company Marinomed says achievements were seen after the first days of the mission: "Our anti-viral nasal spray already entered the European market, China could follow now." Mycosafe, a

well-experienced Vienna company with many international contacts, appreciated the trip. Lukas Porak: "Being back home to Austria and working on the follow-up, we are aware of how really good the trip was."

"The B2B meetings were perfectly organised, and Prof. Rosenberg and myself sat up late into the evening with the business partners." Heinrich Klech of the Vienna School of Clinical Research appreciated the excellent information on the business partners; this delegation trip far exceeded his expectations. He was looking for information and knowledge management in the university sector: "I made very good contacts, it looks very promising for my institution and the future."

Dagmar Siebold of Assign Group, a Vienna-based international working CRO: "This delegation trip brought us a lot of new and qualified contacts within Chinese CROs: initial feedback from China already sounds promising."

At the ChinaBio Partnering Forum in Suzhou, the Austrian companies participated in China's largest biotech partnering exhibition. With the Austrian booth, LISAvienna represented everything Vienna has to offer in the life science field. This is a combined and successful approach for partners and customers.



BOB Phase 1 Best Business Ideas

BOB - Phase 1 honours researchers for innovative ideas. The top three life sciences business ideas were awarded in the first phase of the international business plan competition Best of Biotech. Scientists and students from 15 countries showed their entrepreneurial skills focusing on life sciences and presented their business ideas.

Fifty-four innovative business ideas with economic potential were submitted in the sixth round of Best of Biotech. The Federal Ministry of Economy, Family and Youth funded this start-up initiative to stimulate future-oriented ideas for successfully turning research results into economic assets and to the strengthen Austria as a location for research and industry to make it attractive for the pharmaceutical industry. BOB is run by Life Science Austria (LISA) a programme administered by Austra Wirtschafts Service (aws).

The top three business ideas were awarded the interim award of the two-stage contest with cash prizes:

Genequine Biotherapeutics: Kilian Guse, a researcher from Finland, focuses on the development of innovative biotech drugs for diseases in animals with significant unmet medical needs. Genequine's lead product is a gene therapy for the treatment of paralysis caused by osteoarthritis in horses. This is a market of significant size, which presents a great need for effective therapy.

SIMCharacters: The Vienna SIMCharacters team are Jens-Christian Schwindt (neonatal intensive care), Christoph Kunzmann (design



f.l.t.r.: Ulrike Unterer, Dorothee Van Laer, Michael Hoffmann, Kilian Guse, Nina Sallacz-Berger, Rainer Marksteiner, Johannes Sarx

and animatronics) and Michael Hoffman (financials). They explore a new direction in the development of extremely small patient simulators, combining medical know-how, realistic anatomy and modern animation technology with high technology to save lives.

Vira Therapeutics: The Innsbruck researchers Dorothee von Laer, Lisa Egerer and Sabrina Marozin develop innovative therapeutics for the treatment of viral cancer patients who fail to respond to conventional therapies.

In the second phase, the best business plans will be awarded. The numerous innovations from previous BOBs have resulted in € 211,500 of prize money and 52 start-up companies. The best ideas win attractive cash prizes to the total amount of € 44,500, sponsored by Boehringer-Ingelheim and AFFIRIS.

The special prize for the best medical technology business plan is donated for the second time this year by the cluster initiative LISAvienna.

For more detailed information on BOB: www.bestofbiotech.at or contact n.sallacz-berger@awsg.at

Money & Milestones



FemPower 2012 names three winners and twelve awards (June 2012)

FemPower Call 2012 of ZIT supports projects that are headed by women and/or contribute substantially to the implementation of women and/or in which gender mainstreaming plays a key role. Winners and awardees within the Life Science are: AFFIRIS, Apeiron, EUCODIS Bioscience, Haplogen, Nabriva, Profem and Sanja Selak.



Savira signs collaboration and licence agreement with Roche worth € 240 million to develop small-molecule polymerase inhibitors for the treatment of influenza virus infections. (June 2012)



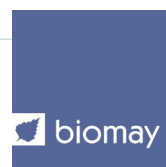
Nabriva Therapeutics and Forest Laboratories sign \$ 25 million agreement (June 2012)



Intercell completes equity private placement of € 15.2 million and a financing transaction consisting of a € 20 million secured loan provided by BB Biotech. (May 2012)



Miracor receives \$ 3.5 million cash infusion by the Austrian Research Promotion Agency ("FFG") to begin pivotal clinical "RAMSES" trial of its PICSO® system. (February 2012)



www.biomay.com

Success Story Biomay AG

Biomay AG is one of the first biotech companies established in Vienna. It was founded in 1984 and is located close to AKH. The company specialises in the research, discovery and development of disease-modifying allergy therapeutics. Biomay develops recombinant allergy vaccines with a superior efficacy and safety profile.

Patients are treated with pharmacotherapy-like antihistamines, which alleviate the symptoms of allergy but cannot stop the progression of the disease. The classical immunotherapy modifies the natural course of the allergic disease by reducing sensitivity to allergens. This kind of therapy consists of a tailored regime of 60 to 100 injections over 3–5 years, which may result in long-term benefits. Contrary to that, Biomay discovered a new approach to specific and disease-modifying therapy, allergen-specific immunotherapy (SIT). This is a therapeutic vaccination based on the administration of modified versions of disease-eliciting allergens to the allergic patient.

Biomay develops recombinant allergy vaccines with a superior efficacy and safety profile, which is based on cutting-edge science for immunotherapy and prophylaxis. The advantage for the patients is an improvement in the quality of life by offering a long-term cure for their disease. And even the treatment itself is much less invasive and less dangerous than the classical immunotherapy. With Biomay's modified therapy, patients who suffer an allergy are treated only seven times by injections within two years: three times before and once after the season and again the following year just three times before the season.

Biomay's lead product is BM32 – a immunotherapy for grass pollen allergy. This allergy vaccine has achieved promising results in a recently published Phase IIa placebo-controlled trial. Seventy patients suffering from grass pollen allergy were given one of three doses of BM32 or a placebo by subcutaneous injections over a period of two months. BM32 is based on an innovative recombinant peptide carrier technology. This leads to fewer injections and fewer side effects compared to other immunotherapy treatments. The vaccine significantly reduced allergy-related nasal symptoms in the study group.



Dr. Rainer Henning, CEO Biomay

The environmental challenge chamber study also showed that BM32 significantly reduced skin reactivity to grass pollen as demonstrated by skin prick testing. Henning pointed out that these exciting data validate their scientific hypothesis that Biomay's vaccines based on the proprietary recombinant peptide carrier technology induce the production of protective antibodies against allergenic proteins contained in grass pollen, which are the root cause of the disease.

This lead product will be pushed forward in the development by Biomay. Currently a grass pollen allergy Phase IIb trial is being initiated. About 180 patients in 6 countries across Europe and 11 sites are being tested with BM32 under natural pollen exposure over two pollen seasons. Results are expected in fall 2014.

Biomay's R&D in innovative allergy therapeutics form the hub of an extensive collaboration network in Austria. This network comprises two major universities (Vienna

and Salzburg), four public private partnership laboratories (Christian Doppler Laboratories) and well over 50 experienced scientists. Within this close cooperation, Biomay's recombinant peptide carrier technology has been developed with Prof. Rudolf Valenta, head of the Christian Doppler Laboratory for Allergy Research at the Medical University of Vienna. The recombinant peptide carrier technology enables an efficient production of IgG antibodies, which are specific for the allergy-causing epitopes of allergen proteins. In order to achieve this allergen-derived B-cell, peptides that lack IgE reactivity are fused to an immunogenic carrier protein and provide the requisite T-cell help.

Prof. Valenta and his team already develop similar vaccines to BM32 for the other major causes of allergies in partnership with Biomay. This project includes vaccines against allergies caused by house dust mites, other pollen, mould and pets. This, of course, connects to Biomay's long-term goal: the development of vaccines candidates for allergies caused by the most important aeroallergen sources (grass, birch, house dust mite, ragweed, Japanese cedar). Biomay works hard to broaden its product pipeline, to advance new products through preclinical and early clinical development, and to bring new product candidates to clinical proof of concept with the aim of partnering them for large late-stage clinical trials, registration and marketing.

In addition, it must be mentioned that Biomay has been selected to present at the prestigious Rodman & Renshaw 14th Annual Healthcare Conference. Only four privately held companies are nominated by this investment bank conference, which takes place in New York on September 9–11, 2012. Biomay will present its concepts to the institutional and private investors at this event to assure the importance of the development of novel allergy treatments.

10th Anniversary of LISAvienna

The Vienna Life Science Cluster LISAvienna celebrates its 10th anniversary.

We would like to invite you to join in celebrating the successes of the life sciences in Vienna and to look into the future.

Honorary Speakers

- Renate Brauner, MA – Vice Mayor of Vienna
- Dr. Ulrike Unterer – Head of Department technological-applied research Ministry of Economy, Family and Youth
- Dr. Sonja Hammerschmid – Rector, University of Veterinary Medicine, Vienna and Co-founder of LISAvienna
- Dr. Joachim Seipelt – COO of AVIR Green Hills Biotechnology AG
- Dr. Hartmut Ehrlich – Vice President, Global Research and Development at Baxter BioScience

Hosts

Peter Halwachs and Johannes Sarx – Managing Directors, LISAvienna

Programme

5:30 pm - Registration
6:00 pm - Speeches
7:15 pm - Buffet and Cocktails

Supported by

Neu Marx

Event location

Rinderhalle Neu Marx (Media Opera), Karl-Farkas-Gasse 19, 1030 Vienna

Date

September 13, 2012



▶ LISAvienna Events Review

Business Treff at AME International

In January 2012 the Vienna-based company AME International GmbH opened their doors to the public interested in life science. Approximately 20 participants gained interesting insight into the daily business of this Viennese enterprise.

AME was established in 1995 and has gained an excellent reputation in implementing and operating complex technology projects in the healthcare sector. The company's unique combination of technical expertise, technology partnerships, and long-standing experience in the optimisation of business processes has transformed it into a significant global player in the area of independent medical technology solutions. After the company introduction, AME gave the opportunity to network and socialise at its attractive headquarters near the Schwarzenberg Platz.

Business Seminar Medtech - changeover EN 60601-1

February 23, 2012 – LISAvienna and the company en.co.tec organised a Business Seminar on the switch from EN 60601-1 to the 3rd edition. After DI Peter Halwachs' and Dr. Hans-Peter Spengler's brief introduction, DI Michael Pözlleitner from TÜV Austria Services GmbH explained the standard EN 60601-1 and the implications for manufacturers of medical products of switching to the 3rd edition. The key issues of this switch were presented by DI Martin Schmid, managing director of en.co.tec Schmid KG.

Ing. Stefan Putz of the W&H Dental Bürmoos introduced his experience regarding this switch in a short best-practice lecture. DI Peter Hagl, managing director of VASEMA GmbH also shared his experiences. After the seminar, the participants had the opportunity to take refreshments and to discuss their experiences with colleagues.

Business Treff at AIT

June 5, 2012 – LISAvienna hosted a business meeting at the AIT Health & Environment Department of the Tech Gate. LISAvienna moves with this series of events across Vienna and organised this meeting at different life science companies. At the AIT H & E Department, numerous members of the LISAvienna-network took the opportunity to learn more about the company and about the research field of molecular diagnostics.

Martin Weber, head of the department since April 2012, presented interesting results from the development of biomarkers and nanosensor systems for medical diagnostics. A particular highlight at this event was the visit to the new clean room laboratory. The Center of Thin Film Technology has expanded recently and the guests had the opportunity to visit the new infrastructure in the center. With snacks and drinks, guests used the opportunity to consolidate and expand their networks.