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“How to Really Use euroPLX” - a Successful Insider’s Best Practices (Part 2/2)

While Part 1 of this article stressed the importance of pre-conference communication and the use of some unique tools at euroPLX, this part highlights the use of post-conference tools, milestones which are important for follow-ups, and common mistakes to be avoided. By Richard Diccio, Chairman of Harvest Moon Pharmaceuticals USA.

In the post conference phase, we have a procedure that lays out milestones:

- having enough non-confidential information to sign a CDA
- exchanging forecasts
- negotiating forecasts to meet batch sizes
- signing a term sheet
- negotiating and signing the definitive license agreement

or, just walking away from a deal.

Establishing these post-conference milestones is as important as the intense pre-conference preparation, and train the BD professional for daily follow-up emails. Benchmark BD professionals always achieve these milestones. The critical quality attributes of a benchmark BD professional have not changed since 2009:

- Having a lack of arrogance but an abundance of patience and vision
- Understanding the business enough to be well-focused and prepared
- Speaking very good English without a thick accent
- Replying quickly to emails, regardless of the local time

- Being well organized to quickly obtain critical term sheet data
- Having the authority, or access to the authority, to sign a binding document

Since 2009 we met a benchmark BD professional worthy of top-twenty status, based solely on her vision. Her territory is MENA and she was frustrated that every

deal for a complex generic had only zone II or zone III ICH stability instead of zone IV and IV-B which is needed for the MENA region. So she convinced her company to build a GMP facility with 20 stability chambers which made her BD in-licensing tasks much easier. She rejected those products that failed zone IV/IV-B stability and encouraged the licensor to re-formulate

to meet the zone IV requirements if they wanted to supply the MENA region.

Another mistake in our article of 2009 was our criticism of delegates asking for carved-out EU territorial licenses for a biosimilar, because it became the norm in 2014 with Celltrion having two licensees and 16 distributors for its eight biosimilars. We learned it is better to have multiple licensees and distributors in a tender territory to guarantee winning the business. Even multinationals will request carved-out territories just to advertise that they have access to all Wave Two mAb biosimilars. The euroPLX conference is the perfect venue to prepare, meet and follow-up multinationals for biosimilar carve-outs.

Not every euroPLX has had 245 companies and 400 delegates like euroPLX 63. We learned that the best euroPLX conferences to attend are always Lisbon (Cascais) and Barcelona. The first-time euroPLX venues have always drawn many relevant delegates for us: Leipzig, Porto, Warsaw, Istanbul, Limassol, and Munich.

Two euroPLX conferences stand out: euroPLX Warsaw in 2009 and euroPLX Malta in 2010. At euroPLX Warsaw we recognized the need

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Generic version of Iressa® available

Synthon will submit its dossier for a generic version of Iressa® (gefitinib) upon data exclusivity expiry in June 2017. We would like to highlight the available dossiers for the generic versions of Tarceva® (erlotinib, currently in registration), Revlimid® (lenalidomide, submission in July 2017) and Zytiga® (abiraterone). Synthon's portfolio is aimed at global out-licensing. Please contact LicensingOut.NL@synthon.com ...or discuss this opportunity with us at euroPLX 64 Vienna!

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Looking for the best Licensing Partner?

Companies that are interested in out-licensing their products for successful marketing in the UK and Republic of Ireland should request to meet with Kent Pharmaceuticals at euroPLX Vienna. Kent Pharmaceuticals is a leading pharmaceutical company looking to further strengthen both its branded and generic pharmaceutical portfolio particularly in the hospital sector. Please contact us at steve.short@kentpharm.co.uk ...or discuss this opportunity with us at euroPLX 64 Vienna!

to intensely prepare for meeting the maximum amount of relevant delegates and we discussed this need with the organizers.

Since that time, RauCon has reorganized euroPLX to fulfill this need and delivered the tools to allow intense preparation for meeting the maximum amount of relevant delegates. Therefore half of our 42 euroPLX meetings have delivered the maximum quality that is possible for that meeting. We were able to accelerate our business development efforts in biosimilars at the euroPLX Malta meeting in 2010; and, biosimilars have become our most profitable business. We will never forget Warsaw and Malta.

First time euroPLX attendees should note that it took us nine years before we recognized the value of using euroPLX as our ultimate business development tool. Unfortunately these proactive BD tools are not available for CPhI or generics meetings in the US and Europe. We need to know proactive collaboration interests and we need to communicate weekly before the actual meeting.

BD People on the Move

* Agilent Technologies Inc.: **Samraat "Sam" Raha**, most recently vice president of global marketing, has been named senior vice president of strategy and corporate development. (Press Release 20 Mar 2017)

* bluebird bio, Inc.: **Joanne Smith-Farrell**, Ph.D., who was Vice President, Business Development Transactions at Merck, Inc., has been appointed as Senior Vice President, Corporate Development and Strategy. (Press Release 20 Mar 2017)

* Coherus BioSciences, Inc. : **Erik Wiberg**, most recently Senior Vice President, Strategy and Corporate Development at Anacor Pharmaceuticals, Inc. has

been appointed as Executive Vice President of Corporate Development. (Press Release 27 Mar 2017)

* Fagron BV: **Ronaldo Steentjes**, most recently Managing Director at Aurex BV, an Aurobindo Pharma company, has been appointed

as General Manager of US based Fagron, Inc (Pers Comm 23 Mar 2017)

* Martin Dow Pharmaceuticals: euroPLX Silver Bell Club Member **Hugues Benevent**, who was until most recently Licensing Manager at Neogen NV, has been appointed as Business Development Director. Mr. Benevent will attend euroPLX 64 Vienna. (Pers Comm 3 Apr 2017)

* Patheon Inc.: **Niels Verschuuren**, who has been Business Development Manager, left the company on 1 March 2017. (Pers Comm 16 Mar 2017)

Company News

* Acquisition: **Abbott** and **Alere Inc.** have agreed to amend the existing terms of their agreement for Abbott's acquisition of Alere. Under the amended terms, Abbott will pay \$51 per common share to acquire Alere, for a new expected equity value of approximately \$5.3 billion, reduced from the originally expected equity value of approximately \$5.8 billion. The transaction is expected to close by the end of the third quarter of 2017, subject to the approval of Alere shareholders and the satisfaction of customary closing conditions, including applicable regulatory approvals. 14 Apr 2017 (www.abbott.com)

* Acquisition: **Astellas Pharma Inc.** has agreed to acquire **Ogedaa** clinical-stage drug discovery company that discovers and develops small molecule drugs targeting G-protein coupled receptors (GPCRs). Under the agreement, Astellas has agreed to pay up to a total of EUR 800 million. 3 Apr 2017 (www.astellas.com)

* Acquisition: **Biogaran** has acquired a foothold in Nigeria with a 95% equity buyout of **Swipha**, the oldest pharmaceutical company in Nigeria. 21 Mar 2017 (www.biogaran.fr)

* Acquisition: **BioLineRx Ltd.**, a

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Generic APIs

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Minakem, part of the MINAFIN group, is a world leading fine chemical company whose core businesses are: Generic APIs, APIs and Intermediates custom manufacturing, building blocks. Please contact Audrey.Lejeune@minakem.com ...or discuss this opportunity with us at euroPLX 64 Vienna!

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Quality meets Science!

Intertek is an analytical contract organization offering its analytical and material technology services to pharma and biopharmaceutical companies under GMP, ISO and GLP requirements. Intertek offers a wide variety of services in API and drug product development and their packaging materials in all clinical phases and a wide range of applications. Intertek has more than 40'000 employees worldwide. Please contact stefan.heck@intertek.com ...or discuss this opportunity with us at euroPLX 64 Vienna

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Farmak is looking for new opportunities

Farmak a.s., is a leading Czech FDA and EU GMP certified producer of APIs with capable R&D activities, exporting its services and products worldwide. We look for new market opportunities in our standard API business and also in the field of FDF based on our APIs already produced or under development. A close collaboration in mutual projects is welcomed. Please contact us at www.farmak.cz ...or discuss this opportunity with us at euroPLX 64 Vienna!

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Opportunity to licence

Douglas Pharmaceuticals is a New Zealand FDA and GMP certified producer of pharmaceuticals exporting to over 35 countries. We are looking for new markets particularly in the Eastern EU where we have had limited contact to date. If you would like to have a chat about in licence opportunities please contact me on carlp@douglas.co.nz ...or discuss this opportunity with us at euroPLX 64 Vienna!

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Accord Healthcare

Accord is one of Europe's fastest growing generic companies with a marketing infrastructure in over 35 European markets covering 97% of the patient population. As market leader in UK, Irish and Spanish Hospitals markets Accord intends to expand its marketing portfolio with simple/complex generics and biosimilars through product acquisition, in-licensing, distribution and other opportunities. Please contact mvasalls@accord-healthcare.com ...or discuss this opportunity with us at euroPLX 64 Vienna!

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How to become the only generic for life

We have generics that are and will remain to be the only generic for the product's entire lifecycle. These "lifetime generics" are available for license. Reply to us at Harvest Moon Pharmaceuticals USA or meet us at euroPLX 64 Vienna to learn more. Be sure to read my article in this and the next issue of the euroPLX Business Developer. Please contact rich.dicicco@harvestmoonpharma.com ...or discuss this opportunity with us at euroPLX 64 Vienna!

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RosenPharma - new products + CMO services

Czech company RosenPharma offers new Nitrofurantoin macrocrystals 50 and 100 mg cps. (DCP registration will start Q1 2018) dossier with BES, Pyrvinium susp. and tabs. dossier (West Europe countries are not free) - OTC anthelmintic for therapy of pinworms by children and adults and CMO of medicines, food supplements and cosmetics /tabs, caps, eff. tabs, sachets, gels,.. in smaller batches too. Please contact pavel_hoder@yahoo.com ...or discuss this opportunity with us at euroPLX 64 Vienna!

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clinical-stage biopharmaceutical company focused on oncology and immunology, has acquired **Agalimmune Ltd.**, a private UK-based company with an innovative, anti-cancer immunotherapy platform. Acquisition consideration consisted of a \$6 million upfront payment, of which \$3 million is in cash and the remainder in BioLineRx shares. Additional future payments may be made based on development and commercial milestones. 23 Mar 2017 (www.biolineRx.com)

* Divestiture: **Cipla Ltd.** has entered into agreements, through its Wholly Owned Subsidiary **Inyanga Trading 386 Proprietary Limited**, with the group compa-

nies of **Ascendis Health Limited, South Africa** for divesting its animal health business in South Africa and Sub-Saharan Africa. Under the Agreements, Cipla will divest its 100% stake in **Cipla Agrimed Proprietary Limited, South Africa** and **Cipla Vet Proprietary Limited, South Africa**. The total consideration of transaction would be ZAR 375 million with potential revision linked to FY2017 performance along with customary adjustment (within the price band of R250m and R500m) in relation working capital and net debt/cash adjustments. The deal is subject to customary closing conditions including approval from competition commission of South Africa and is expected to close in

the next 3 months. 4 Mar 2017 (www.cipla.com)

* Acquisition: **Easton Pharmaceuticals, Inc.** has signed a letter of intent to acquire 100% of revenue producing vaporizer manufacturer **iBliss Inc.**, of Toronto, Ontario, Canada. 23 Jan 2017 (www.eas-tonpharmaceuticalsinc.com)

* Acquisition: **Ethicon** completed its acquisition of **Torax Medical, Inc.**, a privately held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of Gastroesophageal Reflux Disease (GERD). 24 Mar 2017 (www.ethicon.com)

* Acquisition: The **Grünenthal Group** today acquired **Adhesys Medical GmbH** and its US-based

affiliate **Adhesys Medical Inc.**, a Medical Device Startup company focused on the development of adhesives used in surgery. Through this acquisition, Grünenthal has obtained the worldwide development and commercialization rights of an innovative pipeline of surgical sealants together with the underlying technology platform. The first innovative topical skin adhesive is expected to receive European-wide CE Marketing Certification within the next 12 months. 7 Apr 2017 (www.grunenthal.com)

* Licensing: **Hanmi Pharmaceuticals Co. Ltd.** and **MSD** signed a licensing agreement to export ROSUZET (in doses of 10/5mg, 10/10mg, and 10/20mg) to 23 countries except Korea. ROSUZET is a new tablet combining Rosuvastatin and Ezetimibe, used

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for the treatment of hyperlipidemia. It is a specialized medication which, thanks to the double inhibition of cholesterol biosynthesis and its absorption in the liver and the small intestine, is expected to be effective for hyperlipidemia patients unable to be fully treated with single tablets. 6 Jan 2017 (www.hanmipharm.com)

* Acquisition: **Ipsen** has completed its acquisition of global oncology assets from **Merrimack Pharmaceuticals**, in Cambridge, MA., focusing on ONIVYDE® (irinotecan liposome injection) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, in combination with fluorouracil and leucovorin. Ipsen has gained exclusive commercialization rights for the current and potential future indications for ONIVYDE® in the U.S., as well as the current licensing agreements with Shire for commercialization rights ex-U.S. and PharmaEngine for Taiwan. The acquisition also includes the Merrimack commercial and manufacturing infrastructure for Onivyde®, and generic doxorubicin HCl liposome injection. Financial terms of the acquisition include an upfront cash payment of \$575 million to Merrimack Pharmaceuticals, and up to \$450 million upon the approval of potential additional indications for ONIVYDE® in the U.S. 3 Apr 2017 (www.ipsen.com)

* Co-marketing: **Kailos Genetics**, a personalized medicine company offering a leading-edge suite of tools for next-generation sequencing (NGS)-based assays, today announced it has entered into a co-marketing agreement with **Illumina, Inc.** Under the terms of the agreement, Illumina will market and promote the Kailos TargetRich™ line of research solutions for pharmacogenetics targets through its commercial channels. 21 Mar 2017 (www.

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SastoMed is the place where research in the field of modern wound care reaches its limits. We produce and offer high sophisticated wound care products for chronic up to difficult to heal wounds. We are present in 40 countries worldwide and seeking for new territories through distributors to introduce our top products. In case you are interested, please visit our website at sastomed.de or contact f.maes@sastomed.de ...or discuss this opportunity with us at euroPLX 64 Vienna!

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Genepharm S.A offers a wide variety of generic eCTD dossiers covering various therapeutic areas. Most recent developments include products for hypertension or diabetes treatment such as Olmesartan+Amlodipine+HCT and Vildagliptine+Metformine. Genepharm's eCTD dossiers, including Vildagliptin, Lacosamide and Rivaroxaban, are ready for submission in most regions around the globe. Please contact bd@genepharm.com ...or discuss this opportunity with us at euroPLX 64 Vienna!

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AOP Orphan in- and out-licensing

As a leader in the sector of rare diseases, AOP develops and commercializes innovative solutions in the areas of hematology/oncology, cardiology/pulmonology, neurology/psychiatry/metabolic diseases. AOP is interested in partners for the distribution of AOP products as well as in-licensing late stage products as well as active ingredients in the mentioned therapeutic areas for the distribution within Europe. Please contact partnering@aoporphan.com ...or discuss this opportunity with us at euroPLX 64 Vienna!

kailosgenetics.com)

* Acquisition: **Merck**, known as **MSD** outside the United States and Canada, has successfully

acquired a controlling interest in **Vallée S.A.**, a leading privately-held producer of animal health products in Brazil. 22 Mar 2017 (www.merck.com)

* Distribution: **Mochida Pharmaceutical Co., Ltd.** and **United Therapeutics Corporation** have signed an agreement for the exclusive distribution of Tyvaso®, a treatment for pulmonary arterial hypertension (PAH), in Japan. Under this agreement, Mochida will be responsible for obtaining marketing authorization of Tyvaso® and will conduct necessary development actions. 28 Mar 2017 (www.mochida.co.jp)

* Acquisition: **Mylan N.V.** acquired the global rights to the Cold-EEZE® brand cold remedy line from **ProPhase Labs, Inc.** The transaction provides Mylan all assets and rights relating to the Cold-EEZE® brand, including all U.S. businesses and U.S. and international trademarks. The Cold-EEZE® family of brands includes leading over-the-counter cold remedies sold as lozenges, gummies, oral sprays, caplets, QuickMelts® and oral liquid dose forms in the U.S. 29 Mar 2017 (www.mylan.com)

* Licensing: **Novaliq GmbH**, a specialty pharmaceutical company with a disruptive drug delivery platform that transforms poorly soluble drugs into effective therapeutics for ophthalmology, signed a licensing agreement with **AFT Pharmaceuticals** for the commercialization of Novaliq's lead product NovaTears® (treatment of evaporative dry eye disease) in Australia and New Zealand. 21 Mar 2017 (www.novaliq.de)

* Distribution: **Novigenix SA** today announced a commercialization agreement with **Dr Risch Medical Laboratory** for Colox, its blood test for the early detection of colorectal cancer (CRC). 15 Mar 2017 (www.novigenix.com)

* Acquisition: **Organogenesis Inc.**, a commercial leader in the field of regenerative medicine, is expanding beyond wound care with the acquisition of **NuTech Medical**. The newly-combined company will offer a portfolio of advanced and

next generation products for the wound care and surgical biologics markets. 28 Mar 2017 (www.organogenesis.com)

* Acquisition: **Shanghai Fosun Pharmaceutical (Group) Co. Ltd.** signed a definitive agreement under which Fosun Pharma will acquire a majority in **Breas Medical** of Mölnlycke, Sweden, a company active in home mechanical ventilation and sleep treatment. 22 Mar 2017 (www.fosunpharma.com)

* Acquisition: the Executive Board and the Supervisory Board of **STADA Arzneimittel AG** received legally binding transaction offers from two consortia for a public tender offer only subject to the approval of the Executive Board for all outstanding shares of STADA Arzneimittel AG. **Bain Capital** and **Cinven** have presented the most financially appealing offer. The offer estimates STADA'S equity value at approximately Euro 4.109 billion and the company's value at about Euro 5.318 billion. 10 Apr 2017 (www.stada.de)

* Acquisition: **Tessa Therapeutics**, an immunotherapy company dedicated to revolutionizing the treatment of cancer, today announced the full acquisition of **Euchloe Bio**, a biotechnology company specializing in the development and commercialization of antibodies to treat cancer. Euchloe's portfolio includes a number of highly potent checkpoint receptor antagonists and immune system agonists. 23 Mar 2017 (www.tessatherapeutics.com)

* Marketing and Distribution: **Upsher-Smith Laboratories, Inc.** has entered into an exclusive agreement with an emerging pharmaceutical company to market and distribute three generic products. The partner will develop, manufacture and supply the products exclusively for Upsher-Smith, which will market and distribute the products under its own label in the United States. Financial

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terms related to the deal have not been disclosed. 17 Mar 2017 (www.upsher-smith.com)

euroPLX Newcomers to euroPLX 64 Vienna (2)

Since 22 years euroPLX is attended by companies that have never had a delegate at any of the previous euroPLX Conference. See who will attend a euroPLX Conference for the first time:

Based in Voorschoten, The Netherlands, **Allgen Pharmaceuticals** (www.allgen.nl) is an independent pharmaceutical company that is actively engaged in licensing, partnering, developing and marketing late-stage prescription medicines as well as medical devices and consumer brands with a special focus on asthma and COPD.

As an independent, privately-owned pharmaceutical CDMO, **Idifarma** (www.idifarma.com) provides a full range of services covering most of the lifecycle of any pharmaceutical product from first pre-formulation trials to commercial manufacturing: drug formulation, development and validation of analytical methods, quality control and batch release in the EU, stability studies, regulatory affairs, GMP contract manufacturing and packaging for clinical or commercial use. The company is based in Noáin (Navarra), Spain.

Martin Dow Pharmaceuticals (<http://martindow.com>) is an independent CDMO organisation created in France by Pakistani shareholders, with a GMP certified plant providing development, manufacturing, packaging, QC, QA, stability, and warehouse services.

Neolojic (www.neolojic.com) is based in Cairo, Egypt, and provides fully integrated sales and marketing solutions to pharmaceutical manufacturers seeking to gain entry to the Middle East and North African markets.

With headquarters in Miami, Florida, USA, **OPKO Health, Inc.** (www.opko.com) develops, manufactures, and distributes an extensive array of diagnostics and therapeutics for a wide range of indications and conditions. Its subsidiary, OPKO EU is a Barcelona-based company engaged in the development, manufacturing,

marketing, and sale of a robust line of pharmaceutical, nutraceutical, and veterinary products in Europe.

SigmaPharm Laboratories International (www.sigmapharm.com) is headquartered in Bensalem, Pennsylvania, USA. The privately held specialty pharmaceutical company is engaged in

the development, manufacturing and marketing of unique generic and branded products. Its products are developed and manufactured using its proprietary drug delivery systems which can effectively optimize drug solubility, bio-availability and stability.

Based in Tel Aviv, Israel, **Unipharm Ltd.** (www.unipharm.co.il) devel-

ops, manufactures, and markets generic pharmaceuticals for all major therapeutic areas, both off-patent blockbusters and a broad range of niche products within more narrow disease areas.

Insanely Effective Pharma Partnering

euroPLX is the world's most often held partnering conference for the pharma and biotech industries. Because of results delivered.

★ euroPLX 64 Vienna (Austria)

May 29 + 30, 2017

Austria Trend Hotel Savoyen, Vienna

★ euroPLX 65 London (UK)

November 27 + 28, 2017

Sofitel London Heathrow

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