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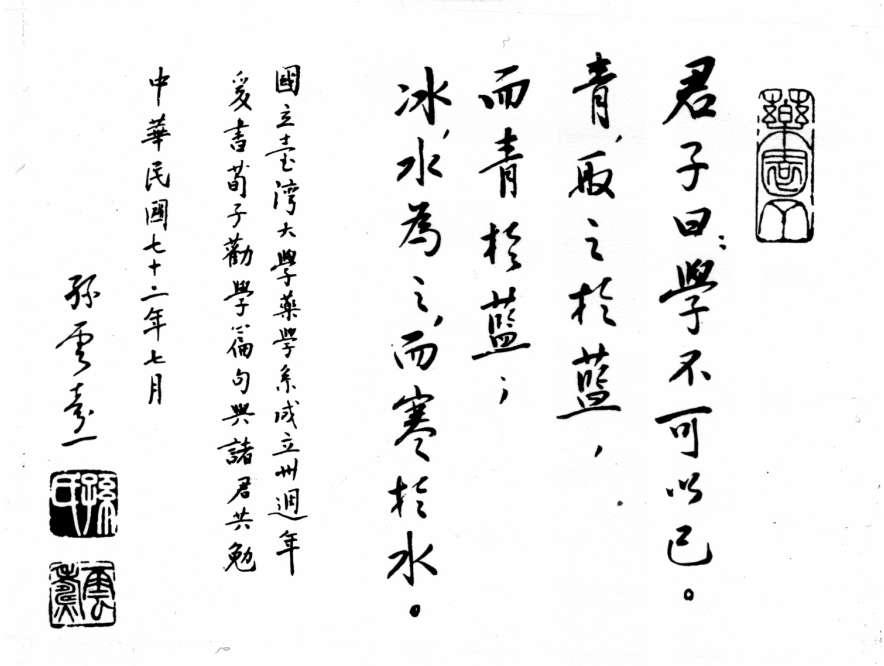

2005 ANNUAL MEETING

NTU School of Pharmacy in the 21st Century

August 5 - 7, 2005

Hyatt Regency San Francisco Airport Hotel
Burlingame, California, USA

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NTU School of Pharmacy Alumni Association - North America
Professor K.C. Wang - New Drug Development Symposium
August 5, 2005

RATIONAL NEW DRUG DESIGN AND DEVELOPMENT AND OTHER BUSINESS OPPORTUNITIES

Symposium Organizers: 湯丹霞，李水盛，吳晉
Chairpersons: 陳志明，湯丹霞
Moderators: 王樂華，湯丹霞，詹勵君，吳晉

8:30 – 8:35 AM Annual Meeting Opening 李敏珠;台大藥學系北美系友會 2004-05 會長

8:35 – 8:40 AM Symposium Opening **陳志明**

8:40 – 9:10 AM Keynote Speech **王光昭教授 (Professor K.C. Wang)**

9:10 – 10:30 AM Session 1

New Drug Design and Discovery (I) - Moderator: 吳晉

蘇銘嘉, 台大藥理科教授

Pharmaceutical Basis in the Development of Agents Against Myocardial Ischemia
Natural Products as a Source

張寬仁, Enhance Biotechnology, Inc.

Delta Receptors Based New Drug Development
Pharmacology and Clinical Applications (DPI 125/221)

王惠珀,長庚大學天然藥物研究所教授兼所長

ADME-Driven Drug Design
The Development of HPW98 and TW01 as Antitumor Agents

RATIONAL NEW DRUG DESIGN AND DEVELOPMENT AND OTHER BUSINESS OPPORTUNITIES

10:30 – 10:45 AM Morning Break

10:45 – 12:30 PM Session 2

Strategies in Modern Drug Screening and Development - Moderator: 王樂華

陳幼敏 , Amgen

Development Candidates Selection
Application of an Integrated Approach

顧曼芹, Wyeth

CMC Consideration and Proactive Defensive Strategy in
New Drug Development to Delay Generic Entry

湯丹霞, Allergan

Global Strategies and Case Reports of
Developing NCE Leads to Human Trials

詹勵君, BMS

Challenges of Transferring Products into Manufacturing

12:30 – 1:30 PM Lunch

RATIONAL NEW DRUG DESIGN AND DEVELOPMENT AND OTHER BUSINESS OPPORTUNITIES

1:30 – 2:50 PM Session 3

Business Opportunities

Innovative vs. Generic Drug Development - Moderator: 詹勵君

林東和, Lotus Pharma

Opportunities for Taiwan Pharma Industry

許中強, Impax Labs

Generic and Brand – Where to Draw the Line?

游丞德, Canyon Pharmaceuticals, Inc.

Canyon Pharmaceuticals – A Specialty Biopharma Start-Up

2:50 – 3:20 PM Afternoon Break

3:20 – 5:20 PM Session 4: Panel Discussion

Is There a Safe and Efficacious New Drug? - Moderator: 湯丹霞

Panelists: **湯丹霞，邱文隆，顧曼芹，王惠珀，林玉葉，李敏珠**

NTU School of Pharmacy Alumni Association - North America
NTU School of Pharmacy in the 21st Century
August 6, 2005

Here We Come!

Session Organizer: 陳基旺

Moderator: 邱文隆

8:30 – 8:40 AM	Session Opening **李敏珠;台大藥學系北美系友會 2004-05 會長**
8:40 – 8:50 AM	Session Introduction 邱文隆
8:50 – 9:10 AM	陳基旺 Introduction of Faculty
9:10 – 9:40 AM	陳基旺 The Strategic Planning for the Long Term Development of NTUSP
9:40 – 10:10 AM	林慧玲 The Proposal for a 6-year Clinical Pharmacy Education in NTUSP
10:20 – 10:30 AM	Morning Break
10:30 – 11:00 AM	高純琇 How to Strengthen the Research Activities in NTUSP
11:00 – 11:45 AM	All-Speaker Panel Discussion, Q&A

Attending NTUSP Faculty:

陳基旺主任

王光昭教授(1957), 陳瓊雪教授(1957), 陳春雄教授(1963)

楊雅雯(1979), 陳燕惠(1981), 高純琇 (1981), 孔繁璐(1989), 林慧玲(1977), 沈麗娟(1993)

NTU School of Pharmacy Alumni Association - North America
Career Pathway Workshop for Pharmacy Graduates
August 6, 2005

To Do, or Not To Do?

Session Organizer: 紀秀怜
Session Moderator: 紀秀怜

1:30 – 1:35 PM	Workshop Opening	**李敏珠; 北美系友會 2004-05 會長**
1:35 – 1:50 PM	**紀秀怜** Overview of U.S. and Taiwan Pharmacy School Graduate Careers	
1:50 – 2:20 PM	**ACADEMIC PATHWAY**	
	鄒淑蓮 孔昭雍	
2:20 – 3:10 PM	**CLINICAL PHARMACY PATHWAY**	
	張麗亞 **孔昭雍** **陳瓊雪教授：** 社區教育推展藥學知識	
3:10 – 3:30 PM	**Afternoon Break**	
3:30 – 4:00 PM	**INDUSTRY PATHWAY**	
	黃文英 **紀秀怜**	
4:00 – 4:20 PM	**GOVERNMENT/FDA PATHWAY**	
	謝淑智	
4:20 – 4:40 PM	**Discussion: Pathway Crossover from All Presenters**	

PHARMACOLOGICAL BASIS IN THE DEVELOPMENT OF AGENTS AGAINST MYOCARDIAL ISCHEMIA

蘇銘嘉 Ming-Jai Su, Ph.D.
Institute of Pharmacology, College of Medicine, National Taiwan University
Taipei, Taiwan.

Abstract

Myocardia ischemia and ischemia/reperfusion are associated with a high incidence of severe ventricular tachycardia and ventricular fibrillation, which is an important problem, especially in patients with acute myocardial infarction or ischemia undergoing percutaneous transluminal coronary angioplasty (PTCA). It has been suggested that overproduction of reactive oxygen intermediates and intracellular calcium overload are two major mechanisms for the reperfusion injury. The incidence of sudden death is related to the occurrence of ventricular fibrillation. The infarct size of myocardium is related to the time period of myocardial ischemia. Over the past decade, several principles from plants or synthesis (including N-allyl –secoboldine, liriodemine, thaliporphine, caryachine, resveratral, cinnamophilin and furoquinoline derivatives) were found to have antiarrhythmic activities in Langendorff perfused rat hearts. According to their electrophysiological effect on isolated cardiac cells, they can be classified into four categories:

(A) Quinidine like action with strong sodium, potassium and calcium channel blocking activities.
(B) A sodium and potassium channel blocker with less calcium channel blocking activities.
(C) A sodium and potassium channel blocker with partial calcium channel agonist activity.
(D) An agent which prolong action potential duration by reducing the rate of sodium channel inactivation.

Among these chemical principles, some were found to have strong antioxidant and free radical scavenpong activities. Others were found to be free of these activities. In the in vitro studies, the ion channel blocking activities of most chemicals are correlated well with their antiarrhythmic activity against ouabain or aconitine-induced arrhythmia. When cardioprotective activity was examined in ischemia or ischemia/reperfusion animals, only some of them were found to have strong cardioprotective activity and can effectively reduce the infarct size of ischemic myocardium and increase survival of animals. Details of their difference in mechanism of action will be discussed

CV

Dr. Ming-Jai Su has had a major career in research and development of cardioprotective agents. In the Institute of Pharmacology, he has held a key leadership position of a cardiac research lab for 16 years. He received Dr. Tsung-Ming Tu's Memorial Research Award in 1994 and received the Award from National Science Council of Taiwan for his technical transfer of his patent drug candidates to pharmaceutical company in 2002. In 2004, he received excellent research award from National Science Council of Taiwan. He earned his B.Sc in pharmacy at Kaoshiung Medical College in 1971 and his Ph.D in pharmacology at National Taiwan University in 1981 and then was promoted as associated professor in 1983 and professor in 1994. From 1983 to 1985, he went to USA and was appointed as Research Assistant Professor of Physiology in University of Pennsylvania. From 1996 to 2002, he was appointed as Chairman of the Department of Pharmacology, National Taiwan University. He is author and coauthor of more than 100 SCI papers. Besides, he has more then 10 patents.

DELTA RECEPTORS BASED NEW DRUG DEVELOPMENT – THE PHARMACOLOGY AND CLINICAL APPLICATIONS (DPI 125/221)

張寬仁 Ken J. Chang, Ph.D. President of Asia-Pacific Operation and CSO
Enhance Biotech, Inc., Durham, North Carolina

Abstract

Opioid receptors are specialized "recognition" proteins located on cell membranes in many organs, including the central and peripheral nervous systems. Currently, three opioid receptors, mu, delta and kappa, have been shown to be important in human physiology. Traditional mu-opioid receptor agonists such as morphine, fentanyl, oxycodone, etc. form the basis for the treatment of patients with moderate-to-severe pain. These mu receptor agonists provide effective analgesia, but displayed multiple, serious and restricting acute and chronic side effects. Respiratory depression, the potentially fatal slowing or cessation of breathing, is the most feared side effect of narcotic analgesia and causes significant concern among prescribers of these agents. Constipation, nausea and vomiting are other side effects that occur with great frequency and often lead to inadequate analgesia as patients limit the use of the drugs to avoid these highly uncomfortable side effects. In the chronic setting, mu agonists also have significant potential for addiction, dependence and abuse. Two areas of these agonists are shown to be useful in preclinical and clinical application: (1) **Mixed Delta/Mu Agonists:** The stimulation of delta- and mu-opioid receptors in combination, and delta receptors alone, leads to specific pharmacological responses that suggest unique treatment approaches to a variety of medical conditions. Using the discoveries regarding mixed delta/mu receptor pharmacology the team has created DPI-125 for acute and chronic pain development programs. (2) **Selective Delta Agonists:** The selective stimulation of delta receptors in animal models leads to specific pharmacological actions that suggest unique treatment approaches to a variety of medical conditions. Additionally, unlike mu receptor agonists or mixed delta/mu agonists, specific delta receptor agonists are not known to be associated with abuse or dependence liability in animal studies. Investigations are currently being carried out in to selective delta receptor agonists in several indications such as urinary incontinence, Parkinson's disease, cardio-protection, depression, and premature ejaculation. We have completed preclinical studies for DPI-221 and plant to submit an IND and conduct Phase 1 trial in 2005 for the indication of urinary incontinence or overactive bladder.

CV

Dr. Chang received his Bachelor of Science degree from NTUSP (10^{th} class) and his Ph.D. degree in Biochemical Pharmacology from the State University of New York at Buffalo, and his postdoctoral training in Medical School, Johns Hopkins University. He founded Ardent Pharmaceuticals, Inc. in Durham, North Carolina, which was merged with Enhance in December 2004. Prior to Ardent Pharmaceuticals, he was a Principal Scientist at former Burroughs Wellcome Co. He currently holds an Adjunct Professor in the Department of Anesthesiology, Duke University Medical Center. He is the co-inventor for 8 issued US patents and 7 pending US patents. Dr. Chang has published approximately 200 papers. He is a co-editor of the book entitled "The Delta Receptor" published by Marcel Dekker, Inc. in 2004. He is an internationally recognized expert in receptor pharmacology, biochemistry and molecular biology. Dr. Chang was a Visiting Professor in the Institute of Biomedical Sciences (IBMS), Taipei, Taiwan in 1989-1990. Dr. Chang received Honor Professorship from Chinese Academia of Medical Sciences and Union Medical University, Beijing, and Dept. of Neurosciences, Shanghai Medical University, Shanghai.

ADME-DRIVEN DRUG DESIGN
THE DEVELOPMENT OF HPW98 AND TW01 AS ANTITUMOR AGENTS

王惠珀 Hui-Po Wang, Ph.D.
Chairperson of the Natural Products Research Institute, Chang Gung University
Taipei, Taiwan, R.O.C.

Abstract

The biological system is full of mechanism for drug delivery, reservation, transformation and clearance, which forms the basis for the majority of drug-host interaction. The mechanism thus becomes wonderful resources for manipulation and optimization of drug action. The success of using D-phenylglycine to prepare intrinsic slow dopamine-releasing prodrugs led us to use this moiety in designing other series of new molecular entities. Azatyrosinamide analogues (HPW98s) not only exhibited cytotoxic but also anti-angiogenesis activities both in in vitro and in vivo studies. Further structural modification of HPW98s led to a second series of TW01 analogues showing more potent inhibitory activities both in vitro and in vivo tumor models. PD/PK optimization of drug activity via ADME-driven chemical and pharmaceutical design will be discussed.

CV

Dr. Wang graduated from National Taiwan University School of Pharmacy. She got Ph. D. from the University of Michigan, U. S. A. and has 5 year working experience as research scientist in Warner-Lambert Parke-Davis Co. She was professor of School of Pharmacy and the Graduate Institute of Pharmaceutical Science, National Taiwan University during 1984-1999, served as the chairperson in 1987-1990. Later on she moved to Chang Gung University in 1999, founded and served as the first chairperson of the Graduate Institute of Natural Products. As a medicinal chemist, her research led to 65 published papers and 40 world patents, particularly in anti-Parkinsonism, anticancer, anti-angiogenesis agents and oral drug delivery system systems. She received the National Outstanding Academic-Industry Collaboration Award in 2000, the 10th National Invention Award in 2001 and the 12th Wang Ming-Ning (王民寧) Outstanding Merit and High Scholastic Achievement to Medical and Pharmaceutical Research in 2002. Professor Wang was appointed the Director General of the Bureau of Pharmaceutical Affairs (BPA), Department of Health in 2002. Harmonization of pharmaceutical regulation for globalization of pharmaceuticals (drugs and medical devices), separation of dispensing from prescription, address the community value in pharmacy service, and public education on rational drug use are among the major tasks of this Bureau. She returns to her teaching position at Chang Gung University as Chairperson of the Natural Products Research Institute in May 2005.

DEVELOPMENT CANDIDATES SELECTION: APPLICATION OF AN INTEGRATED APPROACH

陳幼敏 Yow-Ming C. Wang, Ph.D.
Amgen, Inc. California

Abstract

Pharmaceutical R&D is a very sophisticated system of multidisciplinary collaborations, which is composed of several stages. The first stage of this R&D process is the discovery phase, which has the milestone of identifying development candidates with the highest potential for success in reaching the goal of commercialization. The key collaborating scientific drivers of a discovery program include chemistry, molecular biology, cellular biology, pharmacology, pharmacokinetics, pharmaceutics, and safety. Great technological advancements have recently been made in each of these individual disciplines, but the collaborative nature of the R&D process remains critical for its success. This presentation demonstrates the application of an integrated approach in a case study. The development candidate selection was not only based on the discovery data from in vitro and in vivo pharmacology studies but also based on the safety margin from toxicology studies and projected human exposure from pharmacokinetic modeling. Such integrated approach provides the discovery stage of R&D a guide for multidisciplinary collaborations toward the ultimate goal of a marketable therapeutic agent.

CV

Dr. Yow-Ming Wang is a NTUSP graduate of 1982. She subsequently earned an MS degree in Pharmacology from Kaohsiung Medical University and a PhD degree in Pharmacokinetics and Biopharmaceutics from The Ohio State University. Her primary experience in pharmaceutical R&D has been on the discovery and development of new small molecular entities at Parke-Davis Pharmaceutical Research and Vertex Pharmaceuticals Incorporated. She joined Amgen Inc. in November 2004 and is currently involved in late stage development of therapeutic biologics as well as new small molecular entities. During her 9-year residence at Vertex Pharmaceuticals, Dr. Wang contributed to the success of several discovery projects leading to the selection of development candidate(s) or termination of project(s), and led cross-functional project teams. She also played a key role in establishing departmental infrastructure by overseeing the development of departmental standards and laboratory automation, as well as the implementation and validation of various software in compliance to 21CFR part 11.

CHEMISTRY MANUFACTURE CONTROL CONSIDERATIONS IN NEW DRUG DEVELOPMENT

顧曼芹 M Sherry Ku, Ph.D.
Senior Director, Pharmaceutical Development
Wyeth Research, Pearl River, NY 10965

Abstract

Consideration of active pharmaceutical ingredient (**API**) manufacturability and formulation feasibility must start early as a part of discovery compound evaluation in order to maximize the success rate in clinical trials. It can be frustrating to pharmaceutical scientists to discover that the selected **IND** lead compound is practically undeliverable other than in dimethylsulfoxide (DMSO). The enabling biotechnology of high throughput screening has exacerbated the situation by producing more and more potent but insoluble compounds. Therefore, early evaluation of API manufacturability and formulation feasibility becomes an important part of lead selection.

Wyeth Research has a diverse body of new chemical entities with a wide range of physical chemical and biopharmaceutical properties. A large number of the new API's have shown some trend of polymorphism, which impacts on both bioavailability and pharmacokinetic performance. However, polymorphism is not always predictable based on chemical structures**.** Selection of the thermodynamic stable polymorph requires solid-state characterization of all polymorphs in terms of stability toward humidity (hygroscopicity), temperature and in solvents and aqueous environments. Assurance of pharmacokinetic (PK) consistency is lost when a drug converts to other polymorphs during handling, manufacture and storage and upon ingestion into the GI track. Polymorphism is an important part of new drug development.

Classification of new compounds according to bioavailability and stability liability is an effective tool for prioritization. A compound with poor stability and poor bioavailability is unlikely to be successful. Therefore it should have a low priority for costly clinical studies. For stability evaluation, emphasis is placed on forced degradation to identify stability liability toward acid, base, oxidation, light, heat and humidity. Early identification of degradation products is key to the success of formulation stabilization. With the heightened **ICH** effort, impurity qualification is becoming a major Regulatory hurdle for commercialization.

Low solubility and/or low permeability can lead to poor bioavailability. Wyeth follows the **FDA** Biopharmaceutical Classification Systems (**BCS**) to classify new IND leads. A large number of new IND leads has either low solubility and/or low permeability. A compound with both low solubility and low permeability (BCS class 4) is unlikely to be successful. However, solubility and permeability is difficult to predict based on chemical structures. A two-tier permeability screen based on Caco-2 cell culture and Rat intestinal perfusion models will be described. For a low solubility compound, emphasis is placed on pKa determination and delineation of pH-solubility/partition profile over the entire gastrointestinal pH gradient. The phase I dosage forms can range from solution, suspension, capsule, emulsion, solid dispersion, and nanosystem. Rational formulation selection based on BCS classification will be described.

Lastly, Wyeth is patenting the polymorphs, salt forms, impurities, and formulations with enhanced stability and/or bioavailability for all new compounds.

CHEMISTRY MANUFACTURE CONTROL CONSIDERATIONS IN NEW DRUG DEVELOPMENT

顧曼芹 M Sherry Ku, Senior Director, Pharmaceutical Development, Wyeth Research
Pearl River, NY 10965

CV

Dr. M Sherry Ku is currently Senior Director of Pharmaceutical Development, Wyeth Research, a division of Wyeth Pharmaceutical Company. Her responsibilities encompass activities starting from discovery support, lead selection, phase 0 and IND submission to Clinical Phase 1 and 2 studies until Proof of Concept. With the recent trend of new clinical leads becoming less soluble with poor oral bioavailability. Sherry's emphasis in the past 4 years has been in drug delivery technology to solubilize the 48 new clinical leads discovered in Wyeth in order to improve oral bioavailability or enable intravenous delivery. She received her B. S. Degree in Pharmacy from National Taiwan University in 1978 and a Ph. D. Degree in Pharmaceutics and Pharmaceutical Chemistry in 1983 from The Ohio State University. She joined Berlex laboratories, Division of Schering AG in 1983 and in 1985 moved to American Cyanamid/Lederle Laboratories in Pearl River, New York (Later become Wyeth Research). She was promoted through the ranks of scientist, group leader, section head, associate director, director and senior director in the Pharmaceutical Development Department. In her early years, Sherry developed several commercial products including Suprax, Zosyn/Tazocin, Zebeta, Isovorin, Thioplex, Sonata and most recently Tygacil. She was responsible not only for NDA/PL submission but also technology transfer, process validation and pre-approval inspection. Her research interests include physical pharmacy and biopharmaceutical properties of drugs, specifically in solubility, permeability and stability characterization. She has published in the areas of pKa determination, partition coefficient, hygroscopicity, complexation, solubilization, chemical kinetics, solid state stability, stabilization, lyophilization, formulation optimization and process validation. She is a member of AAPS, APhA and PDA.

GLOBAL STRATIGIES AND CASE REPORTS OF DEVELOPING NMEs TO HUMAN TRIALS

湯丹霞 Diane D-S. Tang-Liu, Ph.D.
Department of Pharmacokinetics and Drug Metabolism
Allergan, Inc., Irvine, CA 92612.

Abstract

Rapid progress in biomedical research has raised new hopes for the prevention and treatment of diseases. However, the path of bringing basic discoveries to clinical applications has not been straightforward or cost-effective. It is therefore desirable, through early human trials, to distinguish drug candidates that are promising from those unlikely to succeed. This presentation will discuss traditional phase 1 dose escalation studies and the recently published FDA draft guidance on exploratory IND.

CV

Diane D-S. Tang-Liu, Vice President of PreDevelopment, Fast Track Development and Clinical Pharmacokinetics, Allergan Inc., received her B.S. in Pharmacy from National Taiwan University and Ph.D. in Pharmaceutical Chemistry from the University of California, San Francisco and completed her post-doctoral training as a NIH Clinical Pharmacology Fellow.

Diane is a recipient of numerous professional awards, with over 80 research publications and over 180 presentations and 30 invited lectures. She was elected to AAPS Fellow in 2002. She is an adjunct professor of Pharmaceutical Sciences at the University of Southern California and serves on a number of scientific advisory boards and committees.

She was President of the Southern California Pharmaceutical Discussion Group, 1994-1995, Chairman of the Board of the South Coast Chinese Cultural Association, 2000-2001, and 2003-2004, and the Founding President of the South Coast Chinese Cultural Foundation. She is a Board Director of Laura's House, dedicated to preventing domestic violence. She received a Spirit of Volunteerism Award from the County of Orange, California (2002), an Award for Chinese Cultural Leadership from the Asian Business Association of Orange County, CA (2003), and a Vision of America Award from the International Channel Networks (2004).

CHALLENGES OF TRANSFERRING PRODUCTS INTO MANUFACTURING

詹勵君 Li-Chun C. Wang, Ph.D.
Associate Director, Global Pharmaceutical Technologies
Bristol-Myers Squibb Pharmaceuticals, New Brunswick, New Jersey

Abstract

The transfer of knowledge, expertise, and technology during pharmaceutical development is essential whether from R&D to manufacturing plant or between manufacturing plants. A seamless transfer results in successful registration batches, no delays in CMC filing, a smooth PAI and assurance of manufacturing ease upon approval. It is important to have standardized methodology to facilitate communication for all parties involved. This presentation will discuss the steps involved in typical transfer of oral and parenteral products to a third party manufacturer plus the challenges and lesson learned in transferring products.

CV

Dr. Li-Chun Wang, Class of 76, has been working in the pharmaceutical industry for 20 years in R&D and Technical Operations. Li-Chun as Associate Director, Global Pharmaceutical Technologies in Bristol-Myers Squibb, was responsible for scale-up and technology transfer of new sterile, liquid, and semisolid products from R&D to commercial production sites, as well as technical support of marketed sterile products for North America and Puerto Rico. Her group conducted more than 10 major new product transfers to BMS sites and third party manufactures. Earlier, she led Apothecon Development, a BMS generic division, to complete five ANDA submissions including one complete parenteral product development. Prior to joining BMS, Li-Chun was Department Head of Pharmaceutics at Carter Wallace, responsible for preformulation, dissolution method development/validation and development/stability testing. Last December, Li-Chun transferred to Worldwide Quality & Compliance to lead a Global Testing Standards integration initiative.

THE OPPORTUNITIES FOR TAIWANESE PHARMA INDUSTRY

林東和 Tong-Ho (Charles) Lin
President, Lotus Pharmaceutical Co., Ltd, Taipei, Taiwan

Abstract

NBA- 姚明
Yankees- 王建民

A. Generics:

Common generics:
Difficult generics: Paragraph IV
Extended Release
Patch
Parenteral
Soft gel

B. Innovative:

Formulation:
NME

CV

Name	Tong-Ho Lin (Charles Lin)
Sex	Man
Date of Birth	28 August, 1953
Nationality	Republic of China
Telephone	(O) 02-27785188
E-mail	charles@lotuspharm.com

GENERIC AND BRAND – WHERE TO DRAW THE LINE?

許中強 Larry Hsu, Ph.D.
President, Impax Laboratories, Inc.

Abstract

For many years generic and branded pharmaceuticals have been two fairly distinct businesses. GPhA and PhRMA have fought each other on just about every issue. The line between these two business sectors, however, has been getting more and more blurred during the past 10 years.

Branded companies often set up generic subsidiaries to market their generic products or establish authorized generics with third parties on a product-by-product basis. Also, generic companies tend move aggressively into branded products' territory. Several generic companies have a significant portion of their sales come from branded products. It has become increasingly difficult for the GPhA and PhRMA to take a position on many issues without first having some internal conflicts.

Is this good or bad for the consumers?

CV

Dr. Hsu co-founded Impax Pharmaceuticals, Inc, a drug-delivery technology based pharmaceutical company, in early 1995 with a partner. In December 1999, Impax Pharmaceutical, Inc. was merged with Global Pharmaceuticals to form a new company, Impax Laboratories. Currently Dr. Hsu is the President of Impax Laboratories, Inc.

Dr. Hsu received his Ph.D. degree in Pharmaceutics from University of Michigan. He worked at Abbott laboratories for 15 years from 1981 to 1995. During the last four years at Abbott, Dr. Hsu was the Director of Product Development in charge of worldwide product development, process engineering, clinical lot manufacturing and production technical support of all dosage forms with a staff of over 250 people. Dr. Hsu received his B.S. degree (class 15th) in Pharmacy from National Taiwan University.

CANYON PHARMACEUTICALS
A SPECIALTY BIOPHARMA START-UP

游丞德 Tony Yu, PharmD, Ph.D.
Co-founder, President & CSO, Canyon Pharmaceuticals

Abstract

Canyon Pharmaceuticals was formed in October, 2003 to focus on thrombosis and thrombin-related therapies. Canyon's first product was desirudin, a recombinant direct thrombin inhibitor, which has been marketed in Europe since 1998 and was recently approved by the FDA in May, 2003. Desirudin was approved for prophylaxis of deep vein thrombosis (DVT). Direct thrombin inhibitor is a new class of anticoagulants which offers the advantage of binding to both free circulating and clot-bound thrombin, and therefore is a more efficient and potent anticoagulant. The recombinant version was cloned and produced in yeast by Ciba (renamed Novartis after merger with Sandoz). Canyon Pharmaceuticals, successfully won the bid to acquire desirudin. The market for anticoagulants is large and attractive. There are only four classes of compounds competing in the anticoagulant market: warfarin, unfractionated heparin and low molecular weight heparin, factor Xa inhibitors, and direct thrombin inhibitors. Canyon projects that the peak sale for desirudin (in 2011) should be around $350 million dollars pre year. Canyon has raised $4.75 million since inception, and is currently seeking $25 million venture funding to purchase the fermentation/purification facility from Novartis and to prepare for the US launch of desirudin by the end of 2006. Opportunities in investing in Canyon is available and will be discussed.

CV

Dr. Yu co-founded Canyon Pharmaceuticals in 2003. He has served as President and Chief Scientific Officer since the inception of the company, with primary responsibility of overseeing Canyon's manufacturing operation in Switzerland. Prior to co-founding Canyon, Dr. Yu was VP of Pharmaceutical Development and Project Management at UPM. He is a formulation scientist with over twenty-five years of R&D and general management experiences in the pharmaceutical industry. During his 14-year tenure at Bristol-Myers Squibb. He was an Associate Director and a Research Fellow of BMS' Pharmaceutical Research Institute where he was awarded BMS' President Award for his outstanding research. His group supported lead candidate compound optimization (from discovery phase to IND) and drug delivery research and formulation development (from IND to NDA). Prior to joining BMS, he spent 3 years at Cooper Laboratories, as Manager and Director, where he built a pharmaceutical development team and a Class 100 clinical manufacturing facility; and 7 years as Sr. Staff Researcher at Syntex where he earned Syntex's Science Award for his outstanding research. Dr. Yu has proven skills in directing solid, semi-solid, and parenteral product development activities. He has participated in numerous IND and NDA filings, as well as product launches. He holds 7 patents in the areas of drug delivery and product stability and has published over 35 papers and book chapters. He was a recipient of the American Pharmaceutical Association's Ebert Prize Award, shortly after he finished his Ph.D. in Pharmaceutics from University of Michigan under Professor Bill Higuchi. Dr. Yu also earned a Pharm.D. from the University of Florida.

Moderator - 王樂華 Laurene Wang-Smith, Ph.D.
Scientific Director, IntellPharma, LLC, Chapel Hill, NC

Laurene Wang-Smith graduated from NTUSP (22nd Class) in 1978. She subsequently received an M.S. degree in pharmacokinetics and biopharmaceutics from the University of Florida, Gainesville; and a Ph.D. degree in pharmacokinetics/clinical pharmacology and drug metabolism from the University of California, San Francisco. Laurene has over 19 years of hands-on, management and leadership experiences in the multidisciplinary areas of pharmaceutical research, development and regulations. Her broad experiences were gained from employment history with two major Pharmas (Burroughs Wellcome, Glaxo Wellcome/GSK) and two start-up companies (Triangle/Gilead Sciences, DarPharma); US FDA; the Clinical Center of the NIH; and international contract research organizations (CROs) and regulatory consulting firms. She has published 36 full articles and over 50 abstracts and served as a reviewer for NIH research and SBIR grants. In April 2004, Laurene founded *Intell*Pharma,LLC, a drug development consulting firm to serve the pharmaceutical and biotechnology industries by providing strategic guidance/direction and hands-on execution in the overall drug development programs, to bring early compounds to INDs and late-stage compounds to NDAs. The primary objective of *Intell*Pharma is to assist the industry in constructing efficient, cost-effective and most-likely successful preclinical and clinical development plans.

Panel Discussion: 邱文隆 Win L. Chiou. Ph.D.
University of Illinois, College of Pharmacy

Win L. Chiou received his B.S. in Pharmacy from NTUSP in 1961 and Ph.D. in Pharmaceutical Chemistry from University of California in 1969. After working as Assistant Professor for 2 years at Washington State University, he moved to the University of Illinois College of Pharmacy in 1971 and retired in April, 2005. He was promoted to Full Professor in 1975, served as Director of Clinical Pharmacokinetics Lab and Director of Graduate Studies in Pharmacy, and Head of Department of Pharmaceutics and Pharmacodynamics. He has served on the editorial boards of 8 scientific journals, on the FDA's Generic Drugs Committee and Expert Panel. He is an elected Fellow in four organizations. His former research was mainly in pharmacokinetics and biopharmaceutics. He was a pioneer in solid dispersions. He is a patent holder of Gris-Peg and Eternal Spring Serum. His current focus of the two companies is cosmetics, dermatology and oral care.

Panel Discussion: 林玉葉 Yueyeh Lin Chang
Sanofi-Aventis Pharmaceuticals, Bridgewater, New Jersey

YueYeh received her BS in Pharmacy from NTUSP in 1973 and a MS in Chemistry from Michigan State University, East Lansing, Michigan in 1978. She has worked in Chemical Abstract Services, Columbus, OH (1979-1986). She currently is the Head at Chemical Library Logistics, Lead Identification Technologies, Science & Medical Affairs, R&D, Sanofi Aventis Pharmaceuticals, Bridgewater, NJ since 1987. YueYeh has published and presented many outstanding papers, book chapters and presentations. Her expertise in compound repository management system and high throughput screening in drug discovery processes has gained wide recognition worldwide.

President, NTUSPAA-NA 2004-2005 and 2005 Annual Conference Chair

李敏珠 Min Chen, M.S., R.Ph.

Associate Director, Division of Drug Risk Evaluation, US FDA

Ms. Min Chen is currently Associate Director of the Division of Drug Risk Evaluation in the Food and Drug Administration's (FDA) Office of Drug Safety. She joined the FDA post-marketing safety office in 1990 as a Safety Evaluator and became Associate Director in 2000. Prior to 1990, she was a project manager in a CDER New Drug review division, and a practicing clinical pharmacist for many years. Min has been involved in all aspects of postmarketing safety surveillance including the development of the Adverse Event Reporting System (AERS) database, Pharmacovigilance Practice and Risk Management Program in the FDA. She is the FDA expert in postmarketing safety reporting regulations and guidances. Internationally, she has been actively involved in ICH Expert Working Groups on topics of developing the standards of postmarketing safety data management.

Symposium Chairperson: 陳志明 Chih-Ming Chen,Ph.D.

CEO, Anchen Inc., and Anchen Pharmaceuticals, Inc.

Irvine, California

Dr. Chih-Ming Chen, received his B.S in Pharmacy (18th class) and M.S in Medicinal Chemistry from NTUSP in 1974 and 1976, respectively. He holds a Ph.D. degree in Pharmaceutics and Pharmaceutical Chemistry from College of Pharmacy, the Ohio State University in 1981. He worked at Bristol Laboratories, Syracus, New York (1982-85), Berlex Laboratories, Cedar Knolls, New Jersey (1985-1988), IVAX Pharmaceuticals, Inc., Miami, Flordia (1988-1992). He established ASAN Laboratories, Inc. (1992-1993) and Co-Founded Andrx Corporation, Davie, Florida (1993-2001). Currently, he is the founder of Anchen Inc., Taipei, Taiwan (2002) and Anchen Pharmaceuticals, Inc., Irvine, California (2003). He was the recipient of The Jack L. Beal Postbaccalaureate Award, College of Pharmacy, The Ohio State University, in 1998.

Symposium Organizer and Moderator: 吳晉 Jinn Wu, Ph.D.

President, XenoBiotic Laboratories, Inc., Plainsboro, New Jersey

Jinn obtained his B.S. in Pharmacy (15th Class) and M.S. degree in Pharmaceutical Chemistry from NTUSP in 1971 and 1975, respectively. He holds a Ph.D. degree in Natural Products Chemistry and Medicinal Chemistry from College of Pharmacy, The Ohio State University in 1979. He was a Postdoctoral Research Associate focused on mass spectrometry and drug metabolism at The Ohio State University from 1979 - 1980. He held key R &D positions at FMC Corporation in Princeton, New Jersey from 1980-1987. He and Ze-Ai (Diana) Chang (also 15th class) established *XenoBiotic Laboratories, Inc.* in 1987. Jinn's areas of expertise and his work at *XenoBiotic Laboratories, Inc.* are in pharmaceutical, agrochemical and biochemical product development, especially in bio-organic analysis, drug metabolism, pharmacokinetic and toxicokinetic studies and assisting pharmaceutical, biotech, and agrochemical companies to meet worldwide regulatory requirements for product registration and regulatory approval. He has published over 50 scientific papers. He was the recipient of The Jack L. Beal Postbaccalaureate Award, College of Pharmacy, The Ohio State University, in 1994. He has served as President for ACPA , NTUSPAA-NA (2002-2003).

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NTU School of Pharmacy Alumni Association - North America
2005 Annual Meeting Program Schedule
August 5 – 7, 2005

AUGUST 4, THURSDAY:

5 – 8 PM	Registration	*Regency Foyer*
8 – 10 PM	Evening Social	*Harbour Room*

AUGUST 5, FRIDAY:

7 – 9 AM	Continental Breakfast	*Regency AB*
8 – 10 AM	Registration	*Regency Foyer*
8:30 AM	New Drug Development Symposium	*Grand Peninsula D*
12:30 – 1:30 PM	Lunch	*Atrium*
5:30 PM	Bus to Chinese Restaurant for Dinner	*Hotel Front*
8 – 11 PM	Special Reunion Meeting, if needed	*Harbour Room*

AUGUST 6, SATURDAY:

7 – 9 AM	Continental Breakfast	*Harbour Room*
9 – 12 PM	NTU School of Pharmacy in 21st Century	*Grand Peninsula D*
12 – 1:30 PM	Lunch	*Atrium*
	Board and Faculty Working Lunch	*Oak Room*
1:30 – 5 PM	Pharmacy Graduate Career Path Workshop	*Grand Peninsula D*
1 – 5 PM	Programs Preparation and Rehearsal	*Harbour Room*
6 PM	Banquet Check In	*Poolside Pavilion*
6:30 – 7:30 PM	Dinner Banquet	
7:30 PM	NTUSP Slide Show	
8 PM	Entertainment Programs	

AUGUST 7, SUNDAY:

7 – 9 AM	Continental Breakfast	*Regency AB*
9 AM	Tour #1 – Impax Labs	*Hotel Front*
	Tour #2 – Northern California Coastlines	*Hotel Front*

CONTACT INFORMATION

Volunteers/Hospitality	陳學玫 (916-208-0088)	Registration	洪淑卿 (240-350-2326)
Sat. Entertainment	張麗亞 (562-789-9888)	Drug Development Program	吳晉 (609-721-1930)
Tours	王有章 (650-307-3718)		
	All others 李敏珠 (301-257-1438)		