



Update Analysis

August 2007, Volume 28, Issue 4

Company Analysis

Welcome to the monthly newsletter for *Pharmaprojects*, the Update Analysis. This issue features a Company Analysis article on OneWorld Health, the US's first not-for-profit pharmaceutical organization. We also review the 67th American Diabetes Association annual meeting and the 8th European Congress of Rheumatology. All the usual *Pharmaprojects* highlights follow, including details of 5 new targets, and a selection of news stories from our website included in our new News Digest section. This month's Search Tip shows you how to search for all drugs launched in the UK this year on *Pharmaprojects*.

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www.pharmaprojects.com

Heal the Sick: Stating the Obvious?

With an estimated 2.7 billion people surviving on less than US\$2 a day, the need to provide more affordable medicines to developing countries seems a vital and simple moral concept to support. But as with all such policies that involve as many different parties as this does, a solution is far from easy. Many have disregarded the governmental and political issues involved, and having accepted that charitable donations offer only temporary respites, focus has turned to the source of these medicines, the pharmaceutical companies, in an attempt to reduce the differences in quality of care between nations. Bearing in mind that drug prices have to cover the costs of numerous other projects that did not make it to launch, it is unsurprising that nations with smaller health budgets, or in some cases no budget at all, are struggling to provide medicinal aid.

Positive action has been observed from the pharmaceutical industry, including that of 39 pharmaceutical organizations which dropped legal action against Nelson Mandela's South African Medicines Act of 1997, which introduced laws to 'broaden access to essential, affordable medication', having previously stated that it infringed intellectual property rights. The Act included measures such as the introduction of transparent pricing mechanisms to force pharmaceutical companies to justify their drug prices, generic substitution of all drugs no longer

under patent, the international tendering for medicines in the public sector, and a parallel importation provision that allowed the government to import the same medicine sold by a company or its licensee at a lower price in another country. Public pressure is indeed spurring the pharmaceutical industry to be more charitable, with support for such moves being clearly visible in the results of many opinion polls. In a National Opinion Poll commissioned by the UK Volunteer Services Overseas (VSO) organization in 2001, 87% of people stated that developing countries should pay less for drugs for diseases such as HIV/AIDS.

There are around 8,000 deaths worldwide per day from HIV/AIDS infection alone, and over 14 million per year from all infectious diseases, with the majority being in poorer nations. The Baragmanath Hospital in Soweto, South Africa, is the largest hospital in the world, catering for a population of over 3 million, and is currently unable to provide the HIV/AIDS therapies successfully utilized in richer nations to reduce related deaths, due to a lack of finance. In fact, 80% of patients in developing countries are having to pay for their own medicines, a situation practically unheard of in developed countries that have health subsidies and insurance programmes in place.

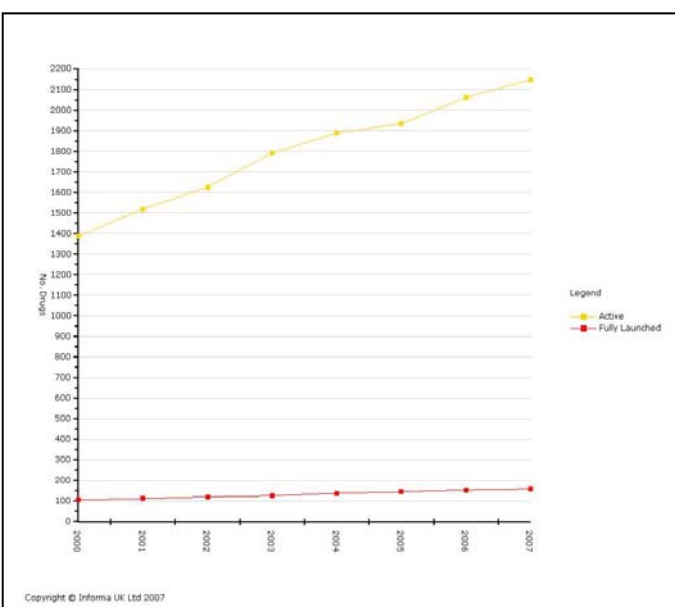


Water borne diseases are very common in the developing world.

The challenge...

has been laid down by numerous charitable and non-profit groups, including in a report published in July 2002 by the VSO, Oxfam UK and Save the Children UK entitled '*Beyond Philanthropy: The pharmaceutical industry, corporate social responsibility and the developing world*'. The report was compiled from the answers to questionnaires sent out to 13 large pharmaceutical companies, and despite only 3 being noted to have answered 'helpfully', the report succinctly manages to organize its suggestions for improvement into 5 key lines of attack: pricing, patents, joint public-private initiatives, research and development, and the appropriate use of medicines. Suggestions include proposals for more flexibility in intellectual property rights, which having a big knock-on effect on drug pricing, could potentially assist with 2 problems at once. It states that donations, while helpful, should not be viewed as sole 'sufficient responses' to the problem, although it is true that long-term donation plans would provide non-profit organizations with a greater facility to introduce larger and more significant changes to achieve their goals.

Besides the monetary problems, a lack of research and development in essential therapeutic areas also poses problems. Many disease areas outside of HIV/AIDS receive little attention, with pharmaceutical focus being driven to more profit-making therapeutic areas such as cancer and neurological disorders. In the past, this has led to many infectious disease treatment programmes being left on the backburner by companies, making the possibility of cheaper and more potent drugs to treat these prominent conditions in poorer communities only a distant hope. Although development in the anti-infective area is lagging behind that of cancer therapeutics, with cancer drug launches having risen



Graph 1: A line graph to demonstrate the increase in launches of anticancer therapies from 2000-2007.

from just under 1400 in 2000 to over 2100 to date (Graph 1), and infection treatments rising in quantity to only just over 1200 from nearly 1000 in 2000 (Graph 2), there has been a steady increase in drug launches in this area.

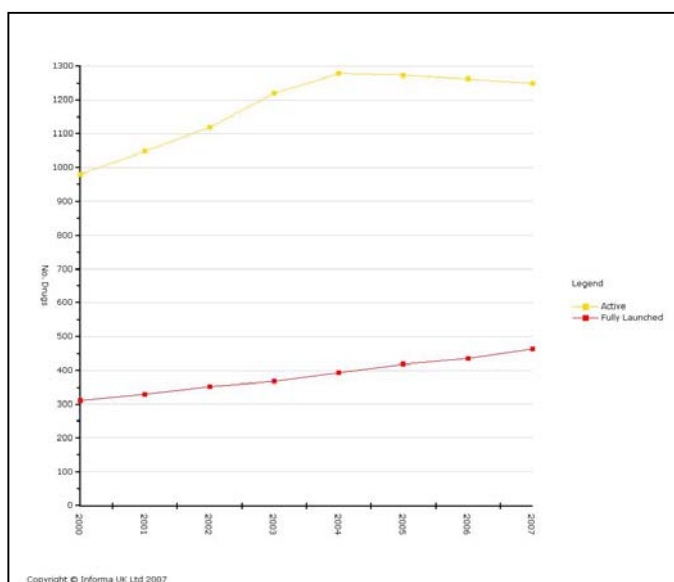
Social entrepreneurs to the rescue - step in Victoria Hale

In one of the grandest attempts to rise to the challenge, Victoria Hale's brainchild, OneWorld Health, was set up in 2000 and became the US's first not-for-profit pharmaceutical organization. Dr Hale, during her career in the US FDA, recognized the scale of the inequities found in global health policies and strived to disprove big pharma's opinion that 'non-profit drug production would never work'. She had a clear and simple mission to serve as a 'positive agent for change by saving lives, improving health and fulfilling the promise of medicine to those in medical need'.

The company's strategy is simple and is possibly why success has quickly followed. Hale devised a strategy of finding anti-infective drugs that have already been developed, but have since been discontinued in order to follow other more profitable lines of research. OneWorld Health found that by in-licensing these drugs, and carrying out the necessary tweaking in order to reduce any adverse events and to optimize potency, they could be developed quickly and more cost effectively, so that provision to poorer communities is feasible. In response to this method of drug development and the potential it holds, OneWorld Health has attracted many heavyweight pharmaceutical partners to assist in its non-profit process, with funding mainly provided by the Bill and Melinda Gates Foundation. With such a colourful, motivated and valuable (both intellectually and monetarily) selection of recruits, OneWorld Health has many more tricks up its sleeve than perhaps any other like-minded attempt has had before.

Sensibly, OneWorld Health has initially focused on 4 areas: leishmaniasis, malaria, diarrhoeal diseases and Chagas' disease, and its hard work in these areas has already paid off.

Within its first 5 years, OneWorld Health achieved the dream: the approval of a visceral leishmaniasis (VL) drug in India in 2005, less than 3 months after the registration submission and having completed the largest ever trial for the disease. The Phase III trial demonstrated non-inferiority against amphotericin, with final cure rates of 94.6 and 98.8%, respectively. Cure rates were also high in paediatric patients and in patients where previous treatment had failed (96 and 98%, respectively). Mild injection-site pain was observed in 55% and transient increases in liver function values in 6% of patients. OneWorld's product promises to be a much cheaper option than the current



Graph 2: A line graph to demonstrate the increase in launches of anti-infective therapies from 2000-2007.

standard of care therapies, with a shorter regimen of 21 days compared to amphotericin's 30-day course. The drug, aminisidine (paromomycin), was developed in collaboration with 7 international partners, including Indian company Gland Pharma, which assisted in manufacturing, and with the Drugs for Neglected Diseases Initiative (DNDi). The off-patent aminoglycoside antibiotic is an established drug, first marketed in 1959. It has an exclusive and well characterized safety profile, and is already used to treat Old World cutaneous leishmaniasis, amoebiasis, cryptosporidiosis and giardiasis.

OneWorld's malaria project has involved a novel approach to the already existing Artemisinin Combination Therapies (ACTs). Artemisinin has been used as a Chinese herbal remedy for thousands of years, and takes over 8 months to cultivate from the wormwood plant. Despite the most commonly used ACT being priced at only US\$2.40 per treatment course, it is still financially unattainable to many developing countries. OneWorld Health is targeting these issues by aiming to produce a stable source of microbially-produced artemisinin to supplement existing sources. With the reduction in manufacturing costs, prices for the therapy should lower dramatically.

The Bill and Melinda Gates Foundation has also given funding for another therapy for malaria, a disease for which there are a few late stage new chemical entities in development. Immtech Pharmaceuticals, for example, is developing pafuramidine maleate, an amidoxine derivative with US orphan drug status. It is in Phase III trials in countries including Angola, the Democratic Republic of Congo and Sudan, and is also in development for sleeping sickness and Pneumocystis jiroveci infection. Initial data from the first 80 patients has demonstrated good safety and efficacy.

There is little active late development in diarrhoeal diseases, with OneWorld Health having the most advanced compound. All others are in early preclinical development, including a compound being developed in a collaboration between Innate Pharmaceuticals and Syngene (Biocon), which is investigating developing virulence blockers that render specific bacteria incapable of causing disease.

Great minds think alike

The objective of redeveloping shelved or already developed drugs is not only utilized by OneWorld Health. CombinatoRx is a US company, which works to 'repurpose' old drugs, producing novel, fixed-dose combinations that are more efficacious or lack the associated adverse effects of single agents. By using the safety data already produced and filing patent applications for the new combinations, reformulation has proven to be faster and more economical than the development of novel pharmaceuticals. Whilst CombinatoRx has 2 drugs in clinical development at present for cancer and arthritis, again demonstrating the apparent unattractiveness of developing candidates for less profitable disease areas. Vice-President Daniel Grau did state in 2004 that the company may begin work on an anti-HIV combination within the coming years, and that if a foundation partner could be identified, it would be willing to avoid patent filing on the new formulation in order to quicken the drug's journey to those in need; a significant step in the right direction. CombinatoRx also has an antiviral project for hepatitis-C in early preclinical development.

Other non-profit organizations have followed suit. The DNDi is a Geneva-based collaboration of 7 previously separate foundations that, whilst not performing any scientific research itself, hopes to provide centralized management for non-profit drug development. This principle is based on the premise that current non-profit drug development is often fragmented and disorganized due to the lack of backing and resources. By providing those missing elements, projects could be more efficient and cost-effective. DNDi plans to spend US\$250million over the coming 12 years to promote therapy development for sleeping sickness, leishmaniasis and Chagas' disease. Initial funding has been provided by the Medecins Sans Frontieres.

In the area of Chagas' disease, Celera Genomics divested its drug candidate, K-777, to OneWorld Health. The cysteine protease inhibitor was in preclinical development by OneWorld Health using funds from the Bill and Melinda Gates Foundation, but was identified as hepatotoxic and, due to the additional concern of the complex manufacturing process, had to be discontinued. Other than OneWorld's own attempts, BioCryst is the only other company according to Pharmaprojects that is actively developing a not-for-

profit therapy. No further information about the research of the benzoic acid and pyridine derivatives has been provided since however. Returning to focus on its other disease areas, OneWorld Health has since published the details of its analysis of the 'landscape' of Chagas' disease in the hope that the sharing of such information will assist Chagas' therapy projects. Whilst this project did not reach fruition, 2 important concepts can be celebrated: profit-motivated pharmaceutical organizations are willing to donate projects to the cause, and OneWorld Health stands by its own concepts and leads by example in sharing information that other companies may withhold for confidentiality reasons.

From pipedream to pipeline

Since the *Beyond Philanthropy* report of 2002, movement has definitely been made by the pharmaceutical industry, even if some proposals are put forward a little gingerly. Celera has proved that companies are willing to give more than money to aid the situation, and CombinatoRx has spoken of wavering the attraction of patenting a drug so that it may reach the patients quicker; important principles that will hopefully be followed.

Helena Vines Fiestas of Oxfam UK comments that "since *Beyond Philanthropy*, the pharmaceutical industry has improved its performance in terms of facilitating access to medicines, if only to manage its reputational risks. Yet, progress is far from sufficient. Furthermore performance varies significantly among companies: a key obstacle is a corporate culture which inhibits innovation and transparency.

"Initiatives such as OneWorld Health, based on bringing to market anti-infective drugs originally abandoned as unprofitable, highlights one of the major market failures of the current drug development model. There is an urgent need to realign financial and public health needs

in drug development."

It must also be accepted that the pharmaceutical companies cannot solve this problem alone. With many of the developing countries' governments unable and perhaps unwilling to share their wealth fairly amongst their citizens, it is understandable that such countries will need to fix their own internal problems before their before a significant difference to their citizens health can be made.

OneWorld Health may only be one small company in an extremely large and financially-motivated industry, but its story is sending ripples throughout the business. Aminisidine IM has not only allowed OneWorld Health to prove non-profit drug development does work, but has done it in a language that all pharmaceutical companies can understand: regulatory approval. With this, an important barrier has been removed, and the concept has been shunted from pipedream to pipeline.

Samantha Richards

Image courtesy of Rajendera Shaw and Oxfam.

Search strategies
Graph 1:
In Trend Analysis:
 [Therapy Grouping] = Anticancer Products
Graph 2:
In Trend Analysis:
 [Therapy Grouping] = Anti-infective Products
Graph by: Active, Ceased or Fully Launched

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Meeting Reports

67th Annual Meeting of the American Diabetes Association, Chicago, 22-26th June

The American Diabetes Association (ADA) held its 67th annual meeting in the gargantuan McCormick Center in Chicago on the 22-26th Jun 2007. The conference covered



Chicago played host to this years ADA annual meeting.

a range of areas of diabetes research, with a programme packed full of presentations, posters and panel discussions. This year, around 13,000 delegates were in attendance, filling the meeting rooms, hallways and exhibition centres. The view of Lake Michigan provided a

scenic backdrop to discussions of the latest findings in diabetes research.

The need for ongoing diabetes research was highlighted by Dr Larry Deeb during his presidential address, in which he stated that there are 225,000 diabetes-related deaths per year in the US alone, with a new case diagnosed every 21 seconds and an estimated 6 million sufferers remaining undiagnosed. He called for a significant increase in research funding following the near 30% increase in prevalence in the US over the past 5 years.

The clinical highlights of the conference included successes in developing treatments for microvascular complications such as neuropathy and retinopathy. A study with fibrate therapeutics found they reduced neuropathy risk by 70%, and trials with Crestor (rosuvastatin) showed that it too could produce significant improvements in neuropathy scores. Preclinical results for the Phase II drug SB-509 demonstrated that it produced an improvement in motor nerve conduction, a result which was validated in a 12-person clinical trial that also showed that an improvement in qualitative sensory test results.

Studies into diabetic retinopathy focused on alternatives to invasive laser photocoagulation treatment. Some of the most promising results utilized VEGFA, which is elevated in retinopathy sufferers, as a target for antibody and Trap therapeutics. Intravitreal peptinib sodium is also under investigation and was reported to abrogate progressive retinopathy without reducing vision.

The finding that diabetic patients have reduced volumes of the hippocampus and amygdala caused a stir, suggesting a link between diabetes and Alzheimer's disease. Intranasal administration of insulin was found to

lead to increased cerebrospinal fluid (CSF) levels of insulin compared to plasma levels, and to increase the removal of amyloid from the intraneuronal space to the CSF and plasma. In some Alzheimer's disease patients and animal models, intranasal insulin was reported to enhance cognitive performance.

Significant findings were presented for the GLP-1 agonist class of antidiabetics, with AVE-0010 showing potential in protecting insulin-producing β cells by reducing apoptosis both alone and in combination with insulin analogues. CJC-1134-PC, a conjugated exendin-4 analogue, effectively lowered glucose levels in a short-term clinical trial. In a preclinical study utilising adeno-associated viral vectors fused to GLP-1, the feasibility of direct pancreatic gene delivery of GLP-1 with long-term expression was demonstrated and was the focus of a great deal of attention.

The major talking point of the meeting was undoubtedly the panel discussion, featuring Dr Steve Nissen and Prof Philip Home, reviewing Dr Nissen's recently-published meta-analysis of the safety and efficacy of GlaxoSmith-Kline's (GSK) Avandia (rosiglitazone). The focus was on the potentially increased risks of cardiovascular events seen with this drug, following Dr Nissen's finding of a 43% increased risk of myocardial infarction. Strengths and flaws of clinical trial designs and of the meta-analysis were discussed. Critics pointed out that negative results published before completion of all long-term trials could have a huge impact on patient dropout rates. An interim analysis of the GSK-sponsored long-term RECORD trial, conducted by Prof Home in light of the meta-analysis, found no significant difference in cardiovascular events. The mixed bag of results were discussed, with Dr Nissen stating he was not calling for a withdrawal or regulatory action, but simply awareness of a potential safety issue and a requirement for an appropriately-designed trial to further investigate this result.

As proceedings were drawing to a close, the lively ADA awards ceremony was held. In a poignant moment, outgoing president Dr Richard Rubin was the recipient of an award for all his efforts in diabetes care as an ADA psychologist, despite his own recent diagnosis of prostate cancer. The packed auditorium was delighted to hear his treatment had been successful, receiving this news with a rapturous round of applause. Dr Donald Steiner, the noted researcher responsible for elucidation of the double chain structure of insulin, was awarded the Albert Reynold Award for Distinguished Training in Diabetes to acknowledge his further contribution to the field by guiding future generations of researchers.

The 67th ADA meeting presented a diverse mixture of medical research with old and new drugs, alongside a

variety of patient-care topics to keep all those in the field well and truly in the know on all current developments in diabetes research and care. The 68th Scientific Sessions, to be held Jun 6-10 2008, in San Francisco, CA, is already hotly anticipated.

Alix Biancardi

8th EULAR, Barcelona 13th-16th June 2007

This year's European Congress of Rheumatology was held in Barcelona, Spain and blessed with its enchanting sunshine. In this stylish and cultural capital, The Centro Convencions International Barcelona attracted over 12,000 attendees from the allied health professional industries worldwide, representing a huge 30% increase from last year. With 1,482 posters on show and 1182 presentations, this year's EULAR schedule was extensive, reflecting the organisation's ongoing commitment to research with an aim to reduce the social and economical burden of rheumatic diseases.

The programme began with a strong plenary open session addressing genetics, spondyloarthropathies, and epidemiology's role in the future treatment of rheumatic disorders. Simultaneously, parallel symposia with invited speakers took place, hosted by the big players in the pharmaceutical industry, including Lilly, Encysive, Roche/GSK, Rottapharm, Wyeth, Pierre Fabre, Pfizer and CombinatoRx to name but a few.



The Centro Convencions International Barcelona.

Among the presentations of cutting-edge research data were findings from ongoing genetic studies that have identified further risk associated with common rheumatic diseases. Data were presented on identification of the IL-23 receptor as a newly-recognised risk factor for ankylosing spondylitis (Abs 2954). Investigators from the Karolinska Institute, Stockholm, reported on findings that the non-HLA loci have a moderate but distinct effect on the genetic risk for rheumatoid arthritis (RA), depending on whether the RA is anti-CCP-positive or -negative.

Thursday saw an overview of RA, covering the concepts of pathogenesis and how this translated to new therapies. A more in-depth analysis was found at the 'Anti-TNF-therapy' session on RA, offering novel presentations describing the use of existing TNF-blocking agents such as etanercept and infliximab (IFX). Ferdinand Breedveld's group from the VUMC found that initial treatment with MTX (methotrexate) + IFX in patients with early-onset RA is more effective than reserving

MTX+IFX for patients who failed previous DMARDs, resulting in more reductions in DAS and HAQ, more patients in clinical remission and more successful discontinuation. This further supports the theory that a window of opportunity exists to achieve an optimal effect of anti-rheumatic treatment. Investigators from UCB presented new data indicating that MTX monotherapy is insufficient compared to a combination with certolizumab pegol 200mg every 2 weeks after 3 initial doses of 400mg, which showed a fast and significant effect in reducing the signs and symptoms of active RA.

On Friday, the 'New Biologics' session discussed data on the value of abatacept (ABA), tocilizumab and rituximab. Bristol-Myers Squibb (BMS) presented data showing a significantly higher flare rate in placebo-treated children and adolescents with active juvenile idiopathic arthritis than in ABA-treated patients and no adverse events of note. A further 1yr double-blind, randomized, placebo-controlled BMS trial of ABA or IFX treatment in RA patients with an inadequate response to MTX showed that at Day 197, clinical benefits were similar with either ABA or IFX. At day 365, the differences in mean scores/responders for the evaluated clinical efficacy measures were better for ABA, suggesting ABA exhibits a more durable response than IFX (3mg/kg every 8wks) through 1 year. A large Phase III study completed by Roche demonstrated the safety and tolerability of tocilizumab, a novel monoclonal antibody targeting IL-6 signalling.

An option to break away from the scientific mania and enjoy the scenery of the city came on Friday evening, when EULAR's 60th anniversary celebration took place at Park Güell. A colourful candyland of gingerbread palaces and Dr Suess-style landscapes located on a bare mountain in the neighbourhood of Gracia was a stunning and uplifting locale for the festivities.

With minds well rested but possibly some sore heads, Saturday began with a special lecture on cytokines and the future of therapeutics in rheumatology followed by poster viewing and some strong scientific parallel sessions. New this year was the inclusion of the most recent EULAR recommendations for the management of rheumatic diseases and presentation of data concerning the agents riloncept and ofatumumab in the session 'Non-TNF Biologics – Clinical aspects'.

This year's congress was a scintillating success and hopefully the benefits of this meeting of great minds will translate from bench to bed, to arthritis patients worldwide. The 9th EULAR congress will take place in Paris, France, on 14-18 June 2008; one can only hope it will provide as inspiring an educational platform for advancing the field of rheumatology as this year.

Una O'Rawe

New Targets

D-amino-acid oxidase

D-amino-acid oxidase is a flavoprotein which uses FAD as its prosthetic group. It is inactive on naturally-occurring L-amino acids. Its biological function is not known; it may act as a detoxifying agent which removes D-amino acids that accumulate during aging. In mice, it degrades D-serine, a co-agonist of the NMDA receptor.

Sepracor is developing D-amino acid oxidase inhibitors for the treatment of schizophrenia.

It belongs to the Enzyme Target Family Group and its EC number is **1.4.3.3**. Its Entrez Gene ID is **1610**.

epoxide hydrolase 2, cytoplasmic

Epoxide hydrolase 2 – also known as soluble epoxide hydrolase – is found in both the cytosol and peroxisomes. It binds to specific epoxides and converts them to the corresponding dihydrodiols. Epoxides play important roles in the regulation of arterial pressure during angiotensin II-dependent hypertension.

Arete Therapeutics is developing compounds that inhibit soluble epoxide hydrolase (sEH) for the treatment of angiotensin II-dependent hypertension and inflammatory diseases.

Epoxide hydrolase 2 belongs to the Enzyme Target Family Group and its EC number is **3.3.2.10**. Its Entrez Gene ID is **2053**.

SLAM family member 6

SLAM family member 6 is a type I transmembrane CD2-related cell surface protein, expressed on Natural killer (NK), T- and B-lymphocytes and thus also termed NTB-A. It may function as a coreceptor in the process of NK cell activation. It also mediates inhibitory signals in NK cells from X-linked lymphoproliferative patients.

Nuvelo is developing a series of MAb's targeting NTB-A for the treatment of B-cell malignancies.

The Entrez Gene ID for NTB-A is **114836**.

voltage-dependent anion channels 2 and 3

Voltage-dependent anion channels (VDAC) are found on the outer mitochondrial membrane. They form voltage-gated pores when incorporated into planar lipid bilayers and are involved in the translocation of adenine nucleotides through the outer membrane. These channels may also function as a mitochondrial binding site for hexokinase and glycerol kinase

PRL-93936 is a 2nd-generation chemotherapeutic targeting voltage-dependent anion channels 2 and 3, under development by Prolexys for the treatment of ras-overexpressing cancers.

Both voltage dependent anion channels belong to the Ion Channel Target Family Group. Their Entrez Gene IDs are **7417** and **7419**, respectively.

New Drug Development Strategies

The following new drug development strategies are also new to the August edition of *Pharmaprojects*.

GPR-109B agonist

Arena Pharmaceuticals is developing GPR-109B agonists for the treatment of atherosclerosis.

GPR-109B agonists are coded in *Pharmaprojects* as **GPR-109B+**

D-amino acid oxidase inhibitor

Sepracor is developing D-amino acid oxidase inhibitors for the treatment of schizophrenia.

D-amino acid oxidase inhibitors are coded in *Pharmaprojects* as **OXI-DAA-**

Companies New to *Pharmaprojects*

Acadia Pharma develops hospital-based pharmaceuticals, and is focused on cancer supportive care and perioperative care.

Acura Pharmaceuticals is focused on the research, development and manufacture of abuse deterrent products.

US-based **Arete Therapeutics** develops first-in-class molecules for the treatment of cardiovascular and inflammatory diseases.

ArmaGen Technologies provides platform technology solutions by targeting small molecules, recombinant proteins and non-viral gene therapies to the brain and spinal cord.

Gene-therapy company, **Advantagene**, develops anticancer immunotherapy drugs that enhance current therapies and provide clinical benefit.

American-based **BioRelix** focuses on the discovery and development of antibiotics that target antibiotic-resistant pathogens.

Gene Signal is researching gene coding in the regulation of angiogenesis, with an initial focus on ophthalmology.

Immune Control is developing 5-HT antagonists for use against lymphoproliferative cancers, autoimmune diseases and transplant rejection.

Iperboreal Pharma researches and develops medicines, hospital products and medical devices for the treatment of critical illnesses.

Swedish company **Moberg Derma** focuses on the development of drugs for the treatment of skin diseases.

Biotechnology company **Modigene** is developing long-acting formulations of therapeutic proteins.

Privately-owned company **MitoPharm** is developing formulations of traditional Chinese medicines for use in aging and poor stamina.

Pacira Pharmaceuticals is a wholly-owned subsidiary of Pacira, and is developing controlled-release injectable products.

Pradama is developing products to treat bone diseases, using its bone-targeting technology.

Indian company **Reliance Life Sciences** develops business opportunities within medical and other biotechnology areas.

Privately-owned **SARcode** develops small-molecule LFA-1 inhibitors to treat inflammatory diseases.

Snowdon discovers and develops compounds for the treatment of cancer, acute and chronic pain and infectious diseases.

Australian Company **Veragenics** develops therapeutics based on antibody and peptide antagonists of endothelial growth factors VEGF-C and VEGF-D.

German biopharmaceutical company, **Xvir Therapeutics**, develops oncolytic adenoviruses for the treatment of multidrug-resistant cancers.

Mergers, Acquisitions, Name Changes and Joint-Ventures

Advancis Pharmaceuticals has changed its name to **MiddleBrook Pharmaceuticals**.

Alteon has acquired Israeli Company **HaptoGuard**.

AstraZeneca has acquired **MedImmune**, which will remain as a subsidiary.

Privately-owned company **Milford Sound Sciences** has changed its name to **Indigo Pharmaceuticals**.

Pioneer Surgical Technology has acquired **Encelle**, which will remain as a subsidiary.

TopoTarget has acquired Swiss pharmaceutical company **Apoxis**.

Wockhardt has acquired French company **Negma Laboratories**, to become the largest Indian pharmaceutical company in Europe.

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Pharmaprojects News Digest

The following news stories are a selection of those listed on our new *Pharmaprojects* website. Go to www.pharmaprojects.com for more of the same, and to subscribe to our e-mail alert service.

Universal influenza vaccine enters Phase I trials

Acambis has announced the initiation of Phase I trials for the first 'universal' influenza vaccine, ACAM-FLU-A, designed to target *all* A strains of the influenza virus, giving it potential as both a pandemic and a seasonal influenza vaccine.

ACAM-FLU-A is a recombinant vaccine that utilizes a hepatitis B core protein to deliver M2e, the extracellular domain of ion channel protein M2, specific to influenza A. Preclinical studies in mice had promising results and have led to the initiation of this Phase I safety and tolerability trial in the US, where ACAM-FLU-A will be given in combination with aluminium hydroxide or QS-21 adjuvant. Results of this trial are highly anticipated for the end of 2007.

Historically all influenza pandemics have been caused by the more virulent A strain of the virus, whereas seasonal influenza is generally caused by both A and B strains.

Acambis' Executive Vice President, R&D, Dr. Michael Watson said that "by removing the need to re-engineer the vaccine every time the virus mutates, a universal vaccine can be manufactured and used any time of year. It could be stockpiled in advance of a pandemic or potentially used routinely to ensure protection against future pandemics".

First Therapeutic Brain Cancer Vaccine Approved

Northwest Biotherapeutics has received authorisation for use of its DCVax-Brain vaccine from the Swiss Institute of Public Health, making it the first commercially-available therapeutic vaccine for brain cancer.

This authorisation was received substantially ahead of schedule, having only been submitted in Feb 2007.

In clinical trials, DCVax-Brain more than doubled the survival time of both newly-diagnosed and recurrent brain cancer patients, with no sign of any serious side-effects, making it a suitable alternative to chemotherapy. Although the median has not yet been reached, survival in newly-diagnosed patients is currently around 33 months, a vast improvement on a median of only 14.6 months with standard therapy. Expressing confidence in DCVax-Brain and of DCVax's potential for treatment of other cancers, Dr Alton Boynton, President and CEO of Northwest Biotherapeutics said, "We look forward to being able to bring DCVax-Brain to patients

in additional countries, and to applying our DCVax technology to many other cancers, including five for which we already have FDA clearance to begin clinical trials".

The vaccine, personalized by combining the patient's dendritic cells with cancer biomarkers derived from the patient's own tumour, is the first of its kind available commercially and is expected to be launched in the third quarter of 2007. EU and US applications are planned for early 2009, following the expected completion of a pivotal US Phase II trial in 141 patients.

Tuberculosis vaccine trials are initiated.

For the first time in over 80 years, mid-stage clinical trials in tuberculosis (TB) patients are underway with a completely new kind of TB vaccine developed by researchers at Oxford University, the UK, and supported by the Wellcome Trust. The Phase II trial is being conducted in South Africa, where TB is widespread, affecting 1 in 100 infants in the Western Cape alone.

TB is second only to HIV/AIDS as the world's most deadly infectious disease. It affects 9 million people worldwide per year and kills at least 1.7 million. In the UK and Ireland, rates of infection have been steadily increasing for 15 years, despite reaching an all time low in the 1980s. Alongside increasing incidence, the mortality rate is expected worsen, especially with the emergence of antibiotic-resistant strains. Disease prevention is therefore of increasing importance globally.

The current standard TB vaccine is the Bacille Calmette-Guérin (BCG), which is prepared from a strain of attenuated live *Mycobacterium bovis*, the bovine tuberculosis bacillus. At best, the BCG vaccine is 80% effective in preventing tuberculosis for up to 15 years; however, this seems to vary geographically. Also it protects against the severe forms of the disease in infants, but is not reliable in preventing pulmonary TB, the most common form of the disease.

The new vaccine, known as MVA85A, is based on a modified vaccinia Ankara virus, and is expected to be given as an adjunct to the BCG vaccination. Previous tests have shown that it produces a very high immune response; now it must demonstrate increased disease prevention. Results of this trial will be highly anticipated by the pharmaceutical industry, where intense speculation regarding potential licensing agreements can be expected, as any such plans have yet to be announced.

Exhibition Calendar

Our team of experienced Account Managers will be demonstrating and promoting the full capabilities of *Pharmaprojects* and other services from Informa Healthcare at a host of international conferences throughout the year. If you would like to brush up on your searching techniques, discuss your subscription requirements or hear about planned product enhancements, then please visit our stand at one of the venues listed below. To schedule an appointment with your dedicated account manager, please e-mail:

For **Europe & ROW:**

For **The Americas:**

For **Japan:**

Guy Morris at guy.morris@informa.com

Anthony Stewart at astewart@pharmabooks.com

Mr T Hirata at info@shiryoken.co.jp

Dates	Conference	Details
IBC's Drug Discovery Technology Confer-		
6-9 August	Drug Discovery and Innovative Therapeutics World Congress	World Trade Center and the Seaport Hotel, Boston, USA For information: http://www.drugdisc.com/ <i>Our Product Development Manager, Alex Westbury, will be presenting a talk about trends in pharmaceutical R&D at this</i>

Further Information

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Search Tip of the Month - Drugs launched in the UK this year

The powerful search facilities available on *Pharmaprojects* can be used for a variety of business purposes. This month's search describes how to search for all drugs launched in the UK this year.

In Drug Profile search, click on country data, country name and type in the desired country.

Pharmaprojects V5.2 (Web) - Quick Search - Drug Profile Search - W/C 29 Jul 2007 [232]

Find: UK

Country Name
Italy
Japan
Jordan
Latvia
Luxembourg
Malaysia
Mexico
Monaco
Netherlands
Netherlands Antilles
New Zealand
No Country
Norway
Peru
Philippines
Poland
Portugal
Russian Federation
Serbia and Montenegro
Singapore
Slovenia
South Africa
South Korea
Soviet Union
Spain
Sweden
Switzerland
Taiwan
Thailand
Turkey
UK
USA
Venezuela
Virgin Islands [British]
World PCT
Yugoslavia

Hits	And/Or	Group	Expression	Value
38526	=	Country Name	=	UK

Click on Country status (Year launched) and type in the year.

Pharmaprojects V5.2 (Web) - Quick Search - Drug Profile Search - W/C 29 Jul 2007 [232]

Find: Logic Value
= 2007
Enter a number between 1960 and 2007.

Hits	And/Or	Group	Expression	Value
38526	=	Country Name	=	UK
92	AND	Country Status (Year Launched)	=	2007
=16				

Visit the *Pharmaprojects* Web site for Search Tips of the Month which have featured in previous issues of the Update Analysis.