THE ONES TO WATCH

A PHARMA MATTERS REPORT.

APRIL–JUNE 2009

Expert review from Thomson Reuters of the most promising drugs changing clinical phase, receiving approval and launched this quarter, based on the strategic data and insight of *Thomson Pharma*®, the world's leading pharmaceutical competitive intelligence solution.

THE QUEEN'S AWARDS FOR ENTERPRISE: INNOVATION 2008

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This quarter's *The Ones To Watch* is notable for the number of novel technologies being used either to administer drugs in more acceptable ways to the patient, and hence more likely to lead to regime adherence (for example, nasal sprays rather than injections), or to deliver the active ingredient more accurately to the target.

In our list of candidates entering phase I trials alone, we highlight Regeneron's VelociSuite, NanoBio's NanoStat™, Intrexon's RheoSwitch Therapeutic System, and proprietary platforms and processes by Osprey Pharmaceuticals and ReceptoPharm.

Further up the pipeline, LIDDS is making use of a ceramic implant called Liproca® Depot to deliver accurate, optimal doses of its anticancer treatment directly into the prostate of sufferers, while Eurand's AdvaTab® and Microcaps technologies are enabling GlaxoSmithKline to redesign its blockbuster Lamictal® as a dissolve-in-the-mouth, taste-masked formulation for patients who find it difficult to swallow tablets.

Most encouragingly of all, we're seeing how new technologies are enabling innovators to repurpose existing drugs for new indications. For example, we highlight in our list of candidates entering phase III this quarter NVA-237, developed by Novartis under license from UK-based Vectura Group and its Japanese partner Sosei.

The active ingredient glycopyrronium bromide is well established as an intravenous treatment for gastric ulcers and as a solution administered to surgical patients to reduce secretions. Novartis noticed that Boehringer Ingelheim and Pfizer's drug Spiriva® (tiotropium bromide), which has a similar pharmacological effect to glycopyrronium bromide, was effective as an inhaled bronchodilator—and gained a substantial market presence. Was the same true of glycopyrronium bromide?

Novartis has developed a dry-powder formulation of glycopyrronium bromide delivered using Vectura's PowderHale technology, which it hopes will become the leading treatment for the smoking-related pulmonary disease that is set to be the world's third largest cause of death by 2020.

Vectura's technology is itself under investigation by a number of other companies, including Boehringer Ingelheim, to produce generic and novel dry-powder inhaled formulations. It may well be that delivery technologies such as this will play as much of a role in shaping the pharmaceutical industry in the new century as new active ingredients.

Meanwhile, let's take a closer look at the five most promising drugs launched or receiving approval, and moving through each of the clinical phases, between April and June 2009.

THE FIVE MOST PROMISING DRUGS LAUNCHED OR RECEIVING APPROVAL

DRUG	DISEASE	COMPANY
Removab®	Malignant ascites	Fresenius Biotech, TRION Pharma
Ilaris®	CAPS	Novartis
Simponi™	Rheumatoid arthritis	Centocor Ortho Biotech, Schering-Plough, Mitsubishi Tanabe Pharma, Janssen Pharmaceutical
Qutenza™	Neuropathic pain	NeurogesX
Lamictal® ODT™	Bipolar I disorder, epilepsy	GlaxoSmithKline

We begin with malignant ascites, the pooling of cancer-containing fluid in the abdomen. In April 2009, the EMEA approved Removab® for the intraperitoneal treatment of malignant ascites in EpCAM-positive carcinoma patients, the first approved treatment for this condition.

The drug is one of the Triomab® series of treatments developed by Fresenius Biotech in collaboration with TRION Pharma for the potential intravenous and intraperitoneal treatment of malignant ascites in various cancers, as well as ovarian cancer, malignant pleural effusion and stomach cancer. It is the only approved antibody targeting EpCAM, an antigen expressed on almost all carcinomas, and the first approved bispecific, trifunctional antibody—as well as the first approved therapeutic antibody invented, developed and produced in Germany.

Whereas traditional monospecific antibodies can only recruit effector cells from the innate immune system, Triomab antibodies can additionally bind and activate the particularly potent group of killer T cells, giving them at least a thousand times more efficacy against tumor cells, and hence requiring far smaller dose regimens.

Cryopyrin-associated periodic syndrome (CAPS) is the name given to a series of life-long auto-inflammatory syndromes caused by a single gene mutation that leads to overproduction of interleukin-1 beta (IL-1 beta). Its symptoms, including debilitating fatigue, rash, fever, headaches, joint pain and conjunctivitis, can be present from birth or infancy, and can lead eventually to deafness, amyloidosis, renal failure and death.

Novartis offers hope with its anti-inflammatory intravenous treatment Ilaris®, which was approved in the US in June 2009 for two forms of CAPS, familial cold auto-inflammatory syndrome and Muckle-Wells syndrome (MWS), in patients over four years of age. The drug was filed in the EU and Switzerland for febrile syndromes including MWS in December 2008, and gained priority review in Australia in June 2009.

Ilaris is a fully human monoclonal antibody that selectively blocks IL-1 beta, unlike traditional treatments that work by suppressing the entire immune system. Its infrequent dosing regime—once every eight weeks—is considerably better than the current standard of care, and of prime importance among young patients who have no alternative but long term treatment. It is well tolerated, with few injection site reactions.

The company is also investigating Ilaris for rheumatoid arthritis, chronic obstructive pulmonary disease (which we will return to later in this edition of *The Ones To Watch*), type 2 diabetes, gout, wet age-related macular degeneration, and as a subcutaneous formulation for systemic juvenile idiopathic arthritis.

In April 2009, both the FDA and Health Canada approved Simponi™ for the treatment of moderately to severely active rheumatoid arthritis in adults (in combination with methotrexate), active psoriatic arthritis in adults (alone or in combination with methotrexate) and for active ankylosing spondylitis in adults. It is the first biologic therapy to be approved concurrently in three distinct rheumatologic diseases.

The drug was developed by Centocor Ortho Biotech, a subsidiary of Johnson & Johnson, in collaboration with licensees Schering-Plough and Mitsubishi Tanabe Pharma, and another Johnson & Johnson subsidiary Janssen Pharmaceutical. It consists of a fully human anti-tumor necrosis factor alpha monoclonal antibody that can be self-administered by a once-monthly subcutaneous injection or intravenous infusion.

European launch is expected either in 2009 or 2010, while Simponi is still in phase II/III development for rheumatoid arthritis in Japan. It is also under investigation for the treatment of ulcerative colitis and Crohn's disease.

Qutenza™ is one of the trade names of NGX-4010, a high-dose transdermal patch of the vanilloid VR1 agonist capsaicin, approved in Europe in May 2009 for peripheral neuropathic pain. Developer NeurogesX expects to launch it in early 2010. According to clinical data, a single topical 30- or 60-minute application of Qutenza directly to the pain site may provide up to three months of localized pain relief, with minimal side effects.

The company is almost investigating the drug as a potential treatment for neuropathic pain, including HIV-associated neuropathies such as distal sensory neuropathy, postherpetic neuralgia associated with shingles, and painful diabetic neuropathy.

There are no currently approved therapies for HIV-associated sensory neuropathy in the US, despite it being a frequent complication of the disease, and it is vital that any treatment that is developed does not interact with the numerous medications HIV patients must already take to manage their condition. We look forward to documenting the results of NeurogesX's trials as they are reported.

Oral medicines are, of course, of limited use if the patient is unable to swallow them. Difficulty in swallowing pills is extremely common, but many patients are unwilling to discuss the problem with their physician out of embarrassment.

GlaxoSmithKline has developed Lamictal® ODT™ to solve the problem in those patients suffering from epilepsy and bipolar disorder. The active ingredient lamotrigine is administered using Eurand's novel AdvaTab® formulation that disintegrates rapidly on the tongue without the need for liquid or chewing, and Microcaps taste-masking technology that encapsulates each drug particle, forming a barrier between the medication and the taste buds even while the drug dissolves.

In May 2009, the product received FDA approval for the treatment of bipolar I disorder and epileptic seizures, based on its demonstrated bioequivalence with standard Lamictal tablets. Lamictal is itself a long-established blockbuster, launched in 1994 and commanding sales of $1.3 billion in the US in 2008.

THE FIVE MOST PROMISING DRUGS ENTERING PHASE III TRIALS

DRUG	DISEASE	COMPANY
NVA-237	Chronic obstructive pulmonary disease	Novartis
arterolane and piperaquine	Malaria	Ranbaxy Laboratories
OncoVEX GM-CSF	Melanoma	Biovex
TRO-19622	Amyotrophic lateral sclerosis	Trophos
farletuzumab	Ovarian cancer	Morphotek

Chronic obstructive pulmonary disease (COPD) is the name given to a number of diseases that narrow the airways—in particular chronic bronchitis and emphysema—as a result of smoking. Unless the sufferer quits their habit, these diseases become progressively worse, leading through symptoms of wheezing and breathlessness to respiratory failure, pulmonary heart disease, and death. They affect more than 6% of the population of industrialized countries, and are the fourth leading cause of death in the US. As smoking spreads into developing countries, it is suggested that by 2020 they will be the third leading cause of death worldwide.

Unlike asthma, it is not easy to reverse the narrowing, though the same kinds of treatments that are used for asthma are also prescribed to sufferers of COPD. Typically inhaled bronchodilators are used, but they often have insufficient duration of action. Novartis believes that NVA-237 (licensed from Sosei and Vectura) has the potential to become the leading bronchodilator used in COPD due to its greater potency and longevity of action.

As we noted in the introduction, the drug is a dry-powder inhaled formulation of glycopyrronium bromide, a muscarinic ACh antagonist, delivered using Vectura's PowderHale technology. Since it is long acting, it needs to be administered once a day only. Phase III trials began in June 2009, with NDA filing expected during 2011.

Resistance is one of the major problems of a disease like malaria. The parasite *P. falciparum* is becoming resistant to many of the currently available therapies, rendering them ineffective. The World Health Organization notes that though the disease infects as many as 300 million people every year, and kills as many as a million of those each year, malarial research is relatively neglected.

Ranbaxy Laboratories, a subsidiary of Daiichi Sankyo, is developing a formulation of arterolane and piperaquine as an alternative both to those ineffective standard therapies and to newer alternatives that are derived from agricultural sources and are hence expensive and difficult to supply in the necessary bulk. The formulation is synthetic, and hence easier to manufacture, more reliable, and cheaper to administer in developing countries.

Ranbaxy aims to market its treatment as a once-a-day therapy to be taken over three days (a total of 3 tablets), compared with the standard treatment of 24 tablets over three days. Again, this should keep down cost and improve patient compliance. A phase III trial began in India, Bangladesh and Thailand in May 2009.

Oncolytics are cancer-destroying viruses designed to replicate and spread within solid tumors, causing the cancer cells to die while leaving the surrounding healthy cells unharmed. April 2009 saw the start of phase III trials for OncoVEX GM-CSF, one in a series of modified oncolytic versions of the herpes simplex virus type-1 developed by Biovex incorporating the company's OncoVEX platform with the granulocyte-macrophage colony stimulating factor (GM-CSF) gene that causes the immune system to destroy metastatic deposits.

The study will assess the treatment's efficacy in sufferers of melanoma. It comes on the back of encouraging phase I and II trials for melanoma, breast, head and neck, pancreatic and colorectal cancer in which multiple patients with metastatic disease progressing at enrollment were declared disease free. The resolved tumors have not been known to recur, and there were few side effects.

Trophos is developing olesoxime for the potential treatment of peripheral neuropathy, amyotrophic lateral sclerosis (ALS), spinal muscular atrophy (SMA), Huntington's disease, Parkinson's disease and multiple sclerosis. It is the first of two candidates for ALS we highlight in this edition of *The Ones To Watch*.

Phase II/III trials began in May 2009, looking at the drug's efficacy and safety in sufferers of ALS. This condition, also known as Lou Gehrig's Disease in the US after the baseball player who died from it in 1939, is probably best known today due to physicist Stephen Hawking, who has suffered from what is likely a variant of ALS for more than 40 years.

The drug is an orally-administered cholesterol-like neuroprotectant which targets the mitochondrial permeability transition pore, preventing the release of apoptotic factors. Phase I studies demonstrated that it is effective, well tolerated with an excellent safety profile, and does not interact with the only currently registered treatment for ALS, riluzole (sanofi-aventis's Rilutek®).

The trials are in part supported by a translation award of almost €6 million from the European Commission. Further substantial grants from France's *Association Francaise contre les Myopathies* and *Agence National de la Recherche* will look at the drug's potential as treatments for SMA and multiple sclerosis respectively.

Returning to cancer, Morphotek began phase III trials in the US in May 2009 of farletuzumab, a humanized monoclonal antibody that blocks the function of folate receptor alpha (FRA), a cell surface protein on tumor cells that has been shown to be expressed on the majority of ovarian cancers. In addition, the drug stimulates the patient's immune system to attack the tumor by destroying those cells which express FRA on their surfaces.

Developed under license from the Ludwig Institute for Cancer Research, the candidate is a potential intravenous treatment both for ovarian cancer and for other epithelial cancer subsets. We expect Morphotek's parent company Eisai to file an NDA in 2012.

THE FIVE MOST PROMISING DRUGS ENTERING PHASE II TRIALS

DRUG	DISEASE	COMPANY
sNN-0029	Amyotrophic lateral sclerosis	NeuroNova
posiphen	Alzheimer's disease	Cenomed BioSciences
MM-111	Cancer	Merrimack
Liproca® Depot	Prostate cancer	LIDDS
emtricitabine/tenofovir disoproxil fumarate/elvitegravir/GS-9350	HIV infection	Gilead Sciences

Turning to our promising drugs entering phase II trials, sNN-0029 is a VEGF agonist and neurogenesis stimulator protein that NeuroNova hopes will provide treatment for moderate to severe stage Parkinson's disease and other central nervous system orphan diseases such as ALS.

Pre-clinical studies showed that sNN-0029 restores motor function and improved neurochemical deficits in sufferers of Parkinson's disease. The therapy consists of short-term, continuous intracerebroventricular delivery of a naturally occurring protein PDGF-BB (platelet-derived growth factor BB), giving PDGF-BB access to the targeted stem and progenitor cells in the lateral ventricular walls of the brain. NeuroNova believes that the drug can not only halt disease progression, but might even reverse it. Even if not, it would be a huge improvement over current standards of care, which merely address the symptoms.

In December 2008, NeuroNova received approval to start a phase I/II safety and tolerability trial in ALS patients. This commenced in May 2009.

Staying with the head, posiphen is the (+)-enantiomer of phenserine and an inhibitor of beta-amyloid precursor protein and beta-secretase, which QR Pharma believes might be a potential treatment of Alzheimer's disease. Phase II trials were underway by June 2009.

Cenomed BioSciences, which has also licensed posiphen from its discoverer TorreyPines Therapeutics, is also studying the drug's efficacy—this time on those exposed to organophosphorus nerve agents such as sarin, soman, tabun and VX gas.

Cenomed BioSciences believes that posiphen can protect against the nerve agent's toxic effects, and potentially restore inactivated muscle and neural cells both in the military and civilians involved in terrorist attacks. This research comes under the US Government's Project BioShield which expedites research on medical treatments for nerve agents, including amended regulations stating that approval can be made based solely on animal trials when human studies could not be conducted ethically.

MM-111 is a fully human monoclonal antibody under development by Merrimack for the potential intravenous treatment of cancers over-expressing ErbB2 such as breast, stomach and lung cancers. It is the first bi-specific antibody binding two different receptors on the same cell (for ErbB2 and ErbB3) to enter clinical development.

Merrimack claims to have used a 'systems biology' approach integrating computational modeling, experimentation and protein engineering to address the complex signaling dynamics between ErbB2 and ErbB3. In 2003, the company's researchers identified ErbB3 as a highly sensitive node in the ErbB signaling network with a dominant role in activating the PI3 kinase pathway believed to be used by cancer cells to sustain survival.

A phase II trial was initiated in Texas in June 2009 to evaluate the safety and pharmacokinetics of MM-111 in patients with Her2 positive breast cancer.

The same month, Swedish life sciences researcher LIDDS began phase I/II trials of Liproca® Depot, an implant containing a novel bio-resorbable, biocompatible controlled-release formulation of the anti-androgen 2-hydroxyflutamide, for the potential treatment of prostate cancer.

The implant is injected locally into the prostate using the well-studied carrier calcium sulfate, enabling optimal concentrations and hence clinical effect of 2-hydroxyflutamide. LIDDS believes this regime will reduce dosing frequency, hence improving patient compliance, and limit the risk for specific drug-to-drug interactions, while having very limited or no side-effects due to significantly reduced liver and systemic drug concentrations. Moreover, the ceramic material of the implant is visible in ultrasound, making it possible to position the dose accurately.

Finally in this section, Gilead Sciences began phase II trials in April 2009 of a once-daily, fixed-dose tablet combination of the nucleoside and non-nucleoside reverse transcriptase inhibitors emtricitabine, tenofovir disoproxil fumarate, elvitegravir, and the antiretroviral boosting agent GS-9350, for the potential treatment of HIV infection.

The studies will enroll 75 HIV-1 infected, antiretroviral treatment-naive adults in approximately 50 sites across the US to evaluate the regimen's safety and efficacy compared to a once-daily regimen of the standard of care Atripla®. The company hopes that its combination will provide a useful alternative to Atripla, itself a combination of Gilead Sciences's tenofovir disoproxil fumarate and emtricitabine with Bristol-Myer Squibb's efavirenz.

THE FIVE MOST PROMISING DRUGS ENTERING PHASE I TRIALS

DRUG	DISEASE	COMPANY
REGN-421	Cancer	Regeneron Pharmaceuticals, sanofi-aventis
NB-1008	Influenza virus infection	NanoBio
OPL-CCL2-LPM	Nephropathy	Osprey Pharmaceuticals
RPI-MN	HIV infection	ReceptoPharm
AD-1001	Solid tumors	Intrexon

At the head of our list of notable candidates entering trials this quarter, Regeneron Pharmaceuticals and sanofi-aventis are developing REGN-421, an antibody targeted against delta-like ligand 4 (dll4), for the potential intravenous treatment of cancer. The drug was discovered using Regeneron's VelociSuite technology.

This is not the first cancer treatment to work by blocking angiogenesis, the growth of new blood vessels that tumors depend on. However, therapies that block vascular endothelial growth factor (VEGF), the key initiator of tumor angiogenesis, are not effective in all patients, and many tumors can become resistant to them. Regeneron believes that also blocking Dll4 will be beneficial to patients who do not respond to VEGF therapy. Paradoxically, studies show that blocking Dll4 causes *more* blood vessels to grow in the tumor, but these are abnormal and rather than support the tumor's growth they choke it.

By February 2009 an IND had been filed, and phase I trials in solid tumors were initiated in April.

Also in April, NanoBio began randomized, phase I trials of NB-1008, a nasal dropper-formulated vaccine comprising inactivated influenza virus antigens mixed with a novel nanoemulsion-based adjuvant, for the potential prevention of influenza virus infection.

The adjuvant means that NB-1008 requires only a small fraction of the normally administered amount of antigen (in trials, as little as 2%) to be effective. Thanks to NanoBio's NanoStat technology, this is uniquely capable of permeating the nasal mucosa, loading the antigen directly into immune-presenting cells. The increased safety of these fractional doses of vaccine could be useful for treating high-risk individuals such as the elderly and young, and may even provide cross-protection against other strains of influenza virus not incorporated within the vaccine. Moreover, it does not need to be administered via injection.

The phase I trials will involve 120 healthy human volunteers in the US. NanoBio is also investigating NanoStat technology for a number of other nanoemulsion-adjuvanted vaccines, including hepatitis B, pandemic influenza, RSV, HIV, pneumococcal, cancer, anthrax and smallpox.

Again in April 2009, Osprey Pharmaceuticals began phase Ib trials for OPL-CCL2-LPM, a recombinant fusion protein targeting the CCR2 receptor and the most advanced of Osprey's candidates based on its proprietary platform of therapeutic leukocyte population modulators (LPMs).

LPMs specifically target the chemokine-activated leuykocytes that drive or maintain a variety of inflammatory and autoimmune disorders, including arthritis, and renal, CNS, pulmonary and cardiovascular diseases. Specifically, the April 2009 trials will study the candidate's efficacy against IgA nephropathy, the most common primary cause of inflammatory kidney disease. Current treatments include blood pressure control, diet and immunosuppressant drugs, but are effective in only 70% of patients.

Preclinical tests demonstrated that OPL-CCL2-LPM has no adverse effects at doses up to 1.5 mg/kg every other day for 15 doses. Data from the phase Ib trial are expected later in 2009.

RPI-MN is an oral formulation of pepteron, a modified cobratoxin as well as a nicotinic acetylcholine receptor antagonist and interferon gamma modulator, under development by ReceptoPharm for the potential treatment of HIV infection. Phase I trials commenced in June 2009.

The company uses a proprietary process of chemical modification to produce candidates containing anticholinergic peptides that recognize the same receptors as nicotine (nAchRs). These receptors are known to be involved in AIDS-dementia, rabies, myasthenia gravis, pain, and Alzheimer's disease. By attaching to the receptors and blocking their activation, ReceptoPharm believes the candidates will prevent viruses from using them as an entry point into the cell—including HIV—with no adverse side effects and no measurable toxicity.

Based on the success of the phase I trials, ReceptoPharm hopes to broaden its investigation into other viruses that cause severe neurological damage, such as encephalitis. A second candidate in the series, RPI-78M, specifically targets multiple sclerosis, and if effective may be the very first biologic MS drug that can be administered orally, eliminating the current requirement for routine injections.

Lastly, we return to cancer to highlight Intrexon's potential solid tumor treatment consisting of intratumorally-injected autologous dendritic cells INcell-1001, adenovirally transduced to inducibly express human IL-12 when activated by an oral small-molecule agent AD-1001.

Again the exciting development here is the company's proprietary technology, known as RheoSwitch Therapeutic System, which controls the in situ timing and level of cytokine expression subsequent to the intratumoral injection of reprogrammed autologous dendritic cells. Preclinical studies suggest that in situ induction is more effective than standard methods of "always on" expression of known anti-tumor cytokines.

A previous phase Ia safety trial in 65 normal healthy male and female volunteers on AD-1001 alone showed that the drug was well tolerated at all dose levels studied, achieved steady-state pharmacokinetics, attained high serum bioavailability levels, and yielded a metabolic half-life consistent with once-a-day dosing. Phase Ib trials of the combination regimen commenced in May 2009.

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