THE ONES TO WATCH

A PHARMA MATTERS REPORT.

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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 Reuters Pharma*™, the world's leading pharmaceutical competitive intelligence solution.

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This edition of The Ones to Watch contains three potential treatments for neglected diseases. sanofi pasteur's ChimeriVax™ Dengue, the world's most advanced dengue vaccine, has entered phase III trials, as has ArTiMist™, a sublingual antimalarial from Star Medical and Eastland Medical Systems for cases of severe and complicated malaria in children. Entering phase II, Sequella's SQ-109 could simplify and shorten tuberculosis treatment for patients in the developing world.

This progress reflects a push in recent years for more R&D into the neglected diseases that predominantly affect the developing world. Patent pools, such as UNITAID's and GSK's, have been set up to allow companies to share intellectual property while the WHO has established a committee to look at new ways of stimulating and incentivizing innovation for neglected diseases.

But some commentators are saying that the 'big three' - HIV/AIDS, malaria and tuberculosis - can no longer be labeled as neglected diseases due to the millions, and in the case of HIV/AIDS billions, of dollars they attract in R&D. Even dengue now has a handful of vaccine candidates in the drug development pipeline. Will the sector now focus on the truly neglected diseases, such as schistosomiasis, filariasis and onchocerciasis?

And oncology continues to command research interest, with a fifth of the drugs described here being anticancer agents. Eisai's Halaven™ can now offer metastatic breast cancer patients a new treatment option at a stage when few are available, while at the other end of the spectrum, Tolerx's TRX-518, commencing phase I trials this quarter, could one day treat melanoma – the most aggressive form of skin cancer.

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 October and December 2010.

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THE FIVE MOST PROMISING DRUGS LAUNCHED OR RECEIVING APPROVAL

DRUG	DISEASE	COMPANY
Teflaro™	Bacterial pneumonia	Forest Laboratories
Halaven™	Metastatic breast cancer	Eisai
Kombiglyze XR™	Type 2 diabetes	AstraZeneca/Bristol Myers Squibb
Brilique™	Acute coronary syndrome	AstraZeneca
Ruconest™	Hereditary angioedema	Pharming/Esteve

We begin this edition of *The Ones to Watch* with **Teflaro™**, an injectable formulation of the broad-spectrum antibiotic ceftaroline fosamil from Forest Laboratories, which acquired the worldwide rights to the drug after its acquisition of Cerexa in 2007. Teflaro received approval from the FDA in October 2010 for the treatment of community-acquired bacterial pneumonia (CABP), including those cases caused by multidrug-resistant *Streptococcus pneumoniae*, and skin and skin structure infections (SSSIs), including those caused by methicillin-resistant *Staphylococcus aureus*.

Both bacterial CABP and SSSI are serious, potentially life-threatening conditions, and new treatments are needed constantly, particularly as bacteria resistance to existing antibiotics continues to increase.

Phase III trials showed that Teflaro had a similar response and cure rate to ceftriaxone in CABP patients and was as effective as vancomycin plus aztreonam against SSSIs.

Teflaro is a prodrug of T-91825, a cephalosporin derivative. Cephalosporins, which interfere with the bacterial cell wall, are the most frequently prescribed class of antibiotics in the world. The drug was launched in the US in January 2011 and *Thomson Reuters Forecast*™ indicates sales will reach $514.7 million in 2015.

Next up is Eisai's **Halaven™** for the intravenous treatment of metastatic breast cancer in patients who have already received at least two treatments for their metastatic disease with an anthracycline and a taxane. These patients have few, if any, treatment options.

Breast cancer is the second most common cancer in women worldwide, causing an estimated 500,000 deaths a year, and rates increase as more countries take up western lifestyles.

Halaven, or eribulin mesylate, received approval in the US in November 2010. The drug is a synthetic analog of halichondrin B, which occurs naturally in the marine sponge *Halichondria okadai*. It inhibits the polymerization of tubulin in cells, thereby arresting the division of cancer cells.

Phase III trials comparing Halaven with physician's choice of treatment in more than 700 women showed significant survival improvements, with average overall survival of 13.1 months compared with 10.7 months. *Thomson Reuters Forecast* predicts sales of $414.6 million in 2014.

Another disease that is on the increase is type 2 diabetes. Almost half of American type 2 diabetics cannot fully control glucose levels with their current medication, and many must take a range of medications daily to treat their diabetes and other associated conditions.

AstraZeneca and Bristol Myers Squibb are hoping to meet some of this need with **Kombiglyze XR™**, their extended-release, fixed-dose tablet combination of the antidiabetic drugs saxagliptin and metformin. The FDA approved Kombiglyze XR™ for type 2 diabetes, alongside diet and exercise, in November 2010, and the drug was launched in the US in January 2011. It has also been submitted for approval in the EU.

Kombiglyze XR is the first once-a-day tablet to combine metformin - the drug of choice for type 2 diabetes - with a dipeptidyl peptidase-4 (DPP-4) inhibitor. DPP-4 inhibitors are thought to increase incretin levels, resulting in the inhibition of glucagon and an associated increase in insulin release.

In phase III trials comparing a range of doses of saxagliptin with placebo in type 2 diabetes patients already receiving metformin, the metformin-saxagliptin combination was superior in a range of outcomes, including AC1 and fasting blood glucose tests.

Thomson Reuters Forecast indicates sales of $459.1 million for 2015.

Also from AstraZeneca, the penultimate drug hitting the market in this edition of *The Ones to Watch* is **Brilique™** (ticagrelor), an oral prophylaxis for atherothrombotic events in patients with acute coronary syndromes (ACS) such as unstable angina and myocardial infarction. ACS patients are at risk of further cardiovascular events.

Brilique was approved in the EU for patients with ACS in December 2010 and is awaiting approval by the FDA. It is an orally active P2T (ADP) receptor antagonist, that prevents blood clotting by inhibiting platelet activity.

The phase III head-to-head PLATO trial established Brilique's superiority over the blockbuster antiplatelet agent Plavix® (clopidogrel) from Bristol-Myers Squibb and sanofi aventis. There were fewer cardiovascular events in patients taking Brilique, including fewer myocardial infarctions, without any more bleeding events. There was an 18% all-cause relative reduction in mortality with Brilique over clopidogrel.

Brilique will compete directly with Plavix, which had sales of $9.3 billion in 2009. However, Plavix loses patent protection in the US in 2012 and is already off patent in some parts of Europe, creating a difficult marketplace for Brilique. Consensus estimates from Thomson Reuters predict Brilique sales of $185 million in 2011, and approximately $1 billion in 2014.

Finally in this section, a treatment for hereditary angioedema (HAE), a disease characterized by sudden and distressing episodes of acute inflammation of the face, extremities, abdomen and airways. The disease affects between 1 in 10,000 and 50,000 people, who experience an average of eight attacks a year, and is characterized by low levels of C1 esterase inhibitor, which normally inhibits the peptidase kallikrein, a key mediator of inflammation.

Few treatments for HAE exist, but now Pharming and Esteve have developed **Ruconest™**, an intravenous infusion of the recombinant C1 esterase inhibitor, conestat alfa. The drug is extracted from the milk of transgenic rabbits using Pharming's proprietary transgenic technology. Ruconest was approved in the EU, Norway, Iceland and Lichtenstein in October 2010 for HAE attacks. It was launched in Denmark and Norway in the same month and submitted to the FDA for approval in December.

Phase III trials in 70 patients found that Ruconest reduced the time to relief at all anatomical locations compared with placebo. Pharming is also developing Ruconest as a prophylactic HAE treatment.

THE FIVE MOST PROMISING DRUGS ENTERING PHASE III TRIALS

DRUG	DISEASE	COMPANY
V-212	Varicella zoster virus infection	Merck and Co
ChimeriVax™ Dengue	Dengue virus infection	sanofi pasteur
AN-2690	Onychomycosis	Anacor
ArTiMist™	Malaria	Star Medical/Eastland Medical Systems
IMA-901	Renal cell carcinoma	immatics

Varicella zoster virus (VZV) commonly causes chickenpox in children and can resurface as shingles in later life. While the infection is generally mild, complications can lead to pneumonia in primary infection and post-herpetic neuralgia after shingles. People with compromised immune systems are at a higher risk of VZV infection than the general population.

In December 2010, Merck and Co began a phase III trial in the US of **V-212**, a heat-treated, inactivated VZV vaccine, for the prevention of shingles. Participants in the trial are all due to undergo a hematopoietic cell transplant - and therefore are vulnerable to infection.

Phase I trials in patients with hematological malignancies showed that V-212 is well-tolerated and induces T-cell responses to VSV.

V-212 is a follow-up to Varivax, developed by Merck and Aventis Pasteur MSD (now sanofi pasteur MSD), a live attenuated varicella virus vaccine indicated for the prevention of chickenpox in individuals 12 months and older, and, as Zostavax, for the prevention of shingles in individuals 60 years of age and older.

Our second agent entering phase III trials is another vaccine, this time for dengue virus, a serious mosquito-borne infection for which there is no current vaccine or treatment. Almost half of the world's population — three billion people — are at risk from infection, and dengue fever is a public health priority in many Latin American and Asian countries.

sanofi pasteur, under license from St Louis University, is developing **ChimeriVax™ Dengue**, a chimeric vaccine targeting all four serotypes of the dengue virus.

A phase III trial was initiated in healthy adults in Australia in October 2010, following phase II trials in the US, Asia and Latin America which demonstrated an immune response against all four virus serotypes after three doses of the vaccine. The Australian trial is the first in a series of global phase III trials and is the first to use vaccine doses produced by industrial-scale processes.

ChimeriVax Dengue, which has FDA Fast Track status, is the world's most clinically advanced dengue vaccine candidate. It uses ChimeriVax™ technology, licensed from St Louis University by Acambis, which was acquired by sanofi pasteur in September 2008. ChimeriVax technology uses a yellow fever vaccine virus to carry the dengue virus genes.

Staying with infectious disease, our next agent entering phase III trials is **AN-2690** from Anacor, a potential topical treatment for onychomycosis, a fungal nail infection - usually of the toenail - that affects approximately 35-36 million people in the US. Onychomycosis is caused by dermatophytes, fungi that infect the skin, hair or nails and involves infection of the nail plate, the nail bed and the sometimes the skin surrounding the nail. The result is discolored, thickened, brittle nails that split, are difficult to trim and make walking while wearing shoes difficult. Existing treatments for onychomycosis either have safety concerns, such as rare but serious liver toxicity in the case of oral therapies, while other topical treatments have low levels of efficacy.

AN-2690 is a topical formulation that has a unique mechanism of action, inhibiting an essential fungal enzyme, leucyl transfer RNA synthetase, which is required for protein synthesis.

In a phase IIa trial, 45% of patients given a 5% dose of AN-2690 had more than 2 mm of clear nail growth and a negative fungal culture, 6 months after treatment. In patients given a higher dose of the drug, 50% achieved this level of efficacy.

Anacor began a phase III trial in December 2010 and results are expected in 2012.

Approximately 40% of the world's population, largely those living in the poorest countries, are at risk of malaria, a parasitic disease which causes one million deaths a year, mainly of children. Without rapid treatment, malaria cases can worsen significantly, but existing tablet formulations of antimalarial drugs can take too long to be absorbed into the bloodstream, while some patients may be suffering from gastrointestinal complications that mean they cannot swallow oral medications.

ArTiMist™, from Star Medical and Eastland Medical Systems, could solve this problem. The artemether-containing combination therapy is administered via a sublingual mouth spray, allowing the active ingredient to reach the bloodstream much faster and reducing the need for long stays in hospitals – lessening the burden on already overstretched health systems. It also does not require refrigeration.

In November 2010, a confirmatory phase III trial was initiated in Rwanda in children up to age five with severe or complicated infections of the most dangerous malaria parasite, *Plasmodium falciparum*. This follows a phase II trial in which ArTiMist was comparable with WHO-recommended intravenous quinine.

Finally, a potential vaccine for the treatment of renal cell carcinoma (RCC) which entered phase III trials in December 2010. **IMA-901**, a therapeutic intradermal vaccine comprising ten synthetic tumor-associated peptide antigens (TUMAPs) is being developed by immatics.

The TUMAPs were identified using immatics' proprietary XPRESIDENT™ platform which analyzes primary tumor tissue for antigens naturally present in human tumors. The TUMAPs have also been shown to activate immune cells such as cytotoxic T cells and T cells against renal cancer cells.

Encouraging phase II trials in advanced RCC patients who had already failed first-line therapy found that pretreatment with a single dose of cyclophosphamide followed by IMA-901 improved survival.

THE FIVE MOST PROMISING DRUGS ENTERING PHASE II TRIALS

DRUG	DISEASE	COMPANY
ADL-5945	Opioid-induced constipation	Adolor
Virus-like particle vaccine	H5N1 influenza	Medicago
ND-0801	Attention deficit disorder/attention deficit hyperactivity disorder	NeuroDerm
SQ-109	Tuberculosis	Sequella
MIM-D3	Alzheimer's disease/ dry eye	Mimetogen

A common side effect of using opioid analgesics for chronic pain is constipation, as opioid receptors in the intestinal tract inhibit peristalsis. An estimated 230 million prescriptions were written for opioids in 2007 in the US alone – about 65 to 75% of the worldwide opioid market. Less than half of those people suffering constipation will find relief via routes such as laxatives.

The only approved drug for opioid-induced constipation (OIC) in the US is Wyeth's Relistor. But while it is being studied in an oral form, it is currently available only as a subcutaneous injection and there are no oral treatments on the market. Adolor, under license from Eli Lilly, is developing **ADL-5945**, an antagonist of the mu opioid receptor for the potential treatment of OIC and other gastrointestinal disorders associated with opioid use.

In October 2010, a proof-of-concept phase II trial was initiated in the US, comparing twice daily administration of ADL-5945 with placebo over four weeks. A second phase II trial began in January 2011. Earlier trials showed the drug is well tolerated.

Medicago is using plants to produce a **virus-like particle (VLP) vaccine** for the prevention of H5N1 avian influenza infection. H5N1 has infected 517 people since 1997, killing 306. The 2009 H1N1 swine flu pandemic highlighted the rapidity with which a virus can spread around the globe, as well as the difficulties in mass producing a vaccine at short notice.

Medicago believes that using plants instead of eggs to produce vaccine virus is less expensive and faster, as well as producing highly effective, cross-protective vaccines. It also avoids supply issues associated with sourcing large amounts of eggs, particularly in times when there may have been massive bird culling associated with an avian influenza outbreak. The company says vaccine production could be initiated within 14 days of isolating a viral genetic sequence, compared with 4-6 months for egg-based production.

A phase II trial of the H5N1 virus-like vaccine began in November 2010. Phase I testing in healthy adults found the vaccine was safe and induced a solid immune response at all tested doses, as well as inducing the production of antibodies against two other H5N1 strains.

The next agent entering phase II trials is for the potential treatment of attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD) in adults. **ND-0801**, a transdermal patch developed by NeuroDerm, entered phase II testing in Israel in November 2010.

Nicotine improves the symptoms of ADD and ADHD, and agonists of the nicotinic receptors are a major area of study for neuronal disorders. But nicotine receptors desensitize after repeated nicotine applications (which is what leads to tobacco addiction), meaning nicotine has limited clinical use.

ND-0801 is believed to work by preventing this desensitization. If this is the case, ND-0801 could be beneficial in the treatment of a range of cognitive and CNS disorders. It is also being investigated for Alzhiemer's disease, schizophrenia and Parkinson's disease.

The potential market for an ADHD/ADD treatment is vast. Diagnosis of ADHD in children increased from 950,000 to 2.4 million between 1990 and 1996, though whether this is due to a genuine increase in cases or simply better diagnosis remains to be determined.

Treatment for tuberculosis is laborious, involving a set of first-line antibiotics which must be taken daily for months. As well as being difficult to deploy in the developing countries where TB is most common, failures in compliance have led to an explosion in antibiotic resistance.

Sequella is hoping that its new antibiotic, **SQ-109**, which began phase II trials in December 2010, could shorten and simplify the TB treatment regimen. It is a second-generation ethambutol (EMB) analog, which inhibits *Mycobacterium tuberculosis* cell growth by interfering with cell wall synthesis – a unique mechanism of action among TB antibiotics.

The phase II trial, which will be carried out in South Africa, Tanzania, Gabon, and Zambia, will test the drug's effectiveness and safety with and without the important TB antibiotic rifampicin. It is being funded by the European and Developing Countries Clinical Trials Partnership (EDCTP).

Preclinical studies found that SQ-109 has excellent activity against both drug-susceptible and -resistant TB bacteria, including XDR-TB strains, in mice. It also enhanced, both in vitro and in vivo, the activity of isoniazid and rifampin, two of the front-line antitubercular drugs, and reduced the time needed to cure mice of TB by 30%.

The drug has both Fast Track and Orphan Drug status from the FDA for tuberculosis and is also being investigated for the treatment of *Helicobacter pylori*-associated duodenal ulcers.

The final drug entering phase II trials this quarter is **MIM-D3**, a small molecule nerve growth factor (NGF) peptidomimetic to treat 'dry eye'.

NGF is a naturally occurring protein in the eye that is responsible for the maintenance of corneal nerves and epithelium, and the production of mucin and tears.

There are few treatments for dry eye disease, one of the most common problems treated by ophthalmologists with an estimated 25-30 million Americans suffering from the condition. Dry eye results in discomfort, vision problems and tear film instability. There is the potential for damage to the surface of the eyeball.

Developer of MIM-D3, Mimetogen, began a phase II trial in people with moderate to severe disease in November 2010 and says that the agent is the first example of using a small molecule neurotrophin mimetic to treat an ocular disease. MIM-D3 is also being investigated for the treatment of Alzheimer's disease.

THE FIVE MOST PROMISING DRUGS ENTERING PHASE I TRIALS

DRUG	DISEASE	COMPANY
AM-152	Fibrosis	Amira
IMA-950	Glioblastoma	immatics/Cancer Research UK
TRX-518	Melanoma	Tolerx
glial growth factor 2 (GGF-2)	Cardiac failure	Acorda
ISIS-APOCIIIRx	Hypertriglyceridemia	Isis

The first agent progressing from the laboratory to the clinic in this edition of *The Ones to Watch* is a potential oral treatment for fibrotic diseases, such as scleroderma and idiopathic pulmonary fibrosis.

There are no FDA-approved treatments for fibrotic diseases, which are characterized by the excessive formation of fibrous connective tissue. In scleroderma, the endothelial cells of the arterioles die and are replaced with collagen and other fibrous material in the organs. Idiopathic pulmonary fibrosis is the fibrosis of the lung interstitium.

Amira Pharmaceuticals is developing **AM-152**, the lead from a series of orally-active lysophosphate-1 (LPA1) receptor antagonists. A phase I trial began in healthy adults in October 2010.

In preclinical studies, agents from the series reduced lung injury, inflammation, fibrosis and vascular leakage in a mouse bleomycin model and protected normal mice from fibrosis. There are currently no LPA1-selective antagonists approved for therapeutic use.

Next up is another outcome of immatics' proprietary XPRESIDENT™ platform. **IMA-950** is a potential vaccine against glioblastoma comprising 11 TUMAPs. immatics is collaborating with Cancer Research UK to conduct a phase I trial of IMA-950 along with radio-chemotherapy in newly diagnosed glioblastoma patients. The trial began in October 2010.

New treatments for glioblastoma, the most common and aggressive form of brain tumor, are needed desperately. Current therapy includes surgery, chemotherapy and radiotherapy, but the disease is difficult to treat and the average survival rate after diagnosis is 14 months.

immatics also plans to collaborate with the US National Cancer Institute on a phase I trial of IMA-950 in glioblastoma patients who have already received successful radio-chemotherapy. Together the two trials should provide information about a range of clinical scenarios.

Staying with cancer, Tolerx is developing **TRX-518**, a humanized monoclonal antibody which inhibits the glucocorticoid-induced TNF receptor (GITR), for the treatment of a range of cancers, including melanoma, the most dangerous form of skin cancer. A phase I trial began in advanced melanoma patients in November 2010.

TX-518 is a first-in-class antibody and immunomodulator, which Tolerx says has tremendous potential to elicit an antitumor response regardless of type. GITR has been recognized as one of the most promising targets in cancer immunotherapy.

A murine analog of TX-518 reduced tumor growth and prolonged survival when administered to mice alongside gemcitabine and complete remission was observed in 65% of mice. Preclinical work also suggests that TX-518 may have a reduced risk of causing serious inflammatory side effects.

Activating GITR on T effector cells with TX-518 enhances the immune system's ability to attack tumors by activating T effector cells and rendering them resistant to suppression by T regulatory cells.

The US CDC estimates that 5.8 million Americans have heart failure, with approximately 670,000 newly diagnosed cases each year. Damaged heart tissue cannot pump blood effectively and the causes of that damage include coronary artery disease, myocardial infarction and high blood pressure.

Existing medications for heart failure, such as niacin, aim to compensate for the heart's reduced ability to pump blood. But these do not directly repair the heart muscle. **Glial growth factor 2** (GGF-2) from Acorda, under license from CeNeS, aims to repair heart muscle by acting on the cardiomycetes themselves and improving their ability to contract.

In December 2010, a phase I trial of intravenous infusion GGF-2 in cardiac failure patients was initiated. In heart failure models, administration of GGF-2 every 48 or 96 hours improved cardiac function for ten days post-treatment.

Acorda is also investigating GGF-2 for a variety of neurodegenerative disorders.

Staying with the cardiovascular system, we round off the fourth quarter of 2010 with a potential treatment for hypertriglyceridemia associated with cardiovascular disease. Hypertriglyceridemia is the presence of high levels of triglycerides – fatty acids – in the bloodstream, which can lead to atherosclerosis.

Isis is developing a series of antisense oligonucleotides which target apolipoprotein C-III (apoC-III), a protein manufactured in the liver that plays an important role in the regulation of triglycerides. Some people cannot produce apoC-III and they have been found to have low levels of triglycerides, suggesting that apoC-III prevents the clearance of triglyerides from the blood and that its inhibition is a promising therapeutic pathway.

Treatments to combat hypertriglyceridemia do exist but they can have undesirable side effects. Isis began a phase I trial of an antisense oligonucleotide against apoC-III, **ISIS-APOCIIIRx**, in December 2010 following encouraging preclinical studies in mouse models which showed that it reduced production of apoC-III mRNA and protein, lowered triglyercide levels and reduced atherosclerosis.

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