

June 2010

www.mstrust.org.uk 14 May 2010

Total PML cases at 49, deaths at 11 as of May 6

Biogen Idec Inc disclosed three more cases of a rare brain infection in multiple sclerosis patients on Tysabri, which it sells with Elan Corp, bringing the total number of cases to 49 as of May 6.

The Cambridge, Mass, biotech company reported no additional deaths in patients that have developed progressive multifocal leukoencephalopathy, or PML, bringing the total to 11.

Tysabri is considered a highly effective therapy for MS, and its growth is important to the future of both Elan and Biogen. But its sales have been slower than originally hoped due to concerns about the risk of PML that led to its temporary withdrawal beginning in 2005.

The overall global rate is about 0.7 per 1,000 patients, the company said, which falls within the 1-in-1,000 rate previously seen in clinical trials and implied on the drug's label.

Of the total cases, 19 were in the US, 27 were in the European Union and three were in other areas. Biogen provides monthly updates on the number of PML cases.

The number of cases is important because if the infection rate climbs too high, sales of the drug may drop.

The most recent update translates to a rate of 1.14 cases per 1,000 for patients on the drug for a year or longer, but rises to 1.62 per 1,000 for those on the drug for two years or longer.

A patient's risk of getting PML increases with the number of monthly infusion that he or she receives, something that the Food and Drug administration highlighted in a January safety update. The agency concluded that the benefits of the medicine continue to outweigh the risks.

The rate is about 1.38 cases per 1,000 patients on the drug for between two and three years.

The incidence is about 0.32 cases per 1,000 patients in those using it for one to two years, and it is almost nonexistent in patients using it for less than a year.

Tysabri's withdrawal from the market occurred after three patients developed PML. The infection re-emerged in mid-2008, and Biogen provided regular updates about the cases until mid-2009. The company began providing monthly updates in mid-February.

Source - Morning Star

www.bbc.co.uk 17 May 2010

Urinary tract infections 'resistant to antibiotics'

Urinary tract infections are becoming increasingly hard to treat because of emerging resistance to current antibiotic drugs, experts warn.

They say the problem is spawned by the overuse of antibiotics in the farming industry which enter the food chain.

Scientists from the University of Hong Kong found evidence suggesting resistance genes are being passed from animals to humans in this way.

Their findings are published in the Journal of Medical Microbiology.

The researchers examined Escherichia coli bacteria, which are responsible for the vast bulk of human urinary tract infections. (UTIs).

Looking at samples from humans and animals they found an identical gene for antibiotic resistance was present.

The gene, called *aacC2*, encodes resistance to a commonly-used antibiotic gentamicin and was found in approximately 80% of the 249 human and animal samples the team studied.

Lead researcher Dr Pak-Leung Ho said: "These resistance genes may possibly spread to the human gut via the food chain, through direct contact with animals or by exposure to contaminated water sources.

"When the resistance genes end up in bacteria that cause infections in humans, the diseases will be more difficult to treat."

Global problem

Although the research was carried out in only one region - Hong Kong - experts say the problem is global.

Dr Ho said: "With the international trading of meats and food animals, antibiotic resistance in one geographic area can easily become global.

"Health authorities need to closely monitor the transmission of resistance between food-producing animals and humans and assess how such transfers are affecting the effectiveness of human use of antibiotics."

Professor Chris Thomas, an expert in bacteria at the University of Birmingham, said doctors in the UK were also seeing resistant strains.

"Antibiotic use in animal husbandry is tightly controlled in Europe.

"But even if the problem is being curbed here, people travelling abroad and moving from community to community will bring resistance with them and it will spread.

"It's a worldwide problem."

He said the resistant infections could be treated with other, sometimes more expensive antibiotics. However, with time, resistance may develop to these too, he warned.

In the UK, it is estimated that one woman in three will have a UTI before the age of 24, and that half of all women will have at least one UTI during their lifetime. They are less common among men.

www.mstrust.org.uk 20 May 2010

Male continence problems focus of new NICE guidance

NICE has set out very specific guidelines for dealing with male continence problems.

Millions of men with continence problems will now have access to better treatments on the NHS, thanks to new NICE guidance.

Around 1 in 4 men aged 40 and above have lower urinary tract symptoms (LUTS), such as needing to urinate urgently or frequently, retention of urine, hesitancy and incontinence.

Symptoms can have a considerable impact on a man's physical, mental and social wellbeing.

They can also be caused by an underlying health concern, such as a urinary tract infection or prostate cancer. There was previously no national guidance for diagnosing and treating these symptoms in adult men, which meant that healthcare professionals were not always using the most effective treatments. The new guideline from the NICE aims to set a national standard so that all patients receive the same high quality treatments wherever they go.

Dr Fergus Macbeth, Director of the Centre for Clinical Practice at NICE said:

"As the prevalence of these symptoms increases with age, and with life expectancy on the rise in Britain, it is vital that the NHS uses the treatments and management techniques that are proven to work best. This is the first time that we have published guidance specifically on how adult men with these symptoms should be diagnosed and treated. We hope that it will help

standardise any variations in clinical practice and encourage more men to seek medical advice if they have any concerns."

Source - Nursing Times

www.mstrust.org.uk 20 May 2010

Sativex deemed approvable by regulators in UK/Spain

It was good news for GW Pharmaceuticals and Spanish partner Almirall this morning after regulators in the UK and Spain agreed that, under the decentralisation procedure, Sativex is approvable in Europe.

Regulatory agencies in both countries agreed that all issues relating to the application to market Sativex (delta-9-tetrahydrocannabinol and cannabidiol) for multiple sclerosis spasticity have been resolved, which means the process has now entered the final stage, which, on completion, will allow national marketing approvals to be issued.

A green light for the drug in the UK (expected in the second quarter) will see GW's books boosted by a £10-million milestone payment from Bayer Schering Pharma, which will market Sativex in the country, while approval in Spain, expected in the second half of this year, will see a further £2.5 million from Almirall, which holds marketing rights in the rest of Europe.

Shares in GW had, however, dipped this morning on the London Stock Exchange after the group's interim results showed a swing into the red, posting a net loss before tax of £2.7 million compared to profit of £4.0 million in the year-ago period.

On the upside, the firm saw revenues (excluding milestones) jump to £11.4 million from £8.1 million in the first half of 2009, with growth driven by sales from its alliance with Otsuka and Sativex, it said.

In addition, GW closed the period with significantly more cash in its back pocket, with £20.4 million at March 31 compared to £11.8 million a year ago, and all-in-all the firm is certainly very upbeat about its future prospects.

"GW is transitioning from a late stage development company to a commercial pharmaceutical business with excellent growth prospects," said the company's chairman Geoffrey Guy, and added that the first half of 2010 has proven to be "the most important in GW's history in which we have made material progress towards Sativex's launch in Europe and generated positive cancer pain data in the US".

"With the first major approvals and launches for Sativex now imminent, the US cancer pain Phase III trial preparation well underway, partners for Sativex secured in key markets, a highly promising earlier stage pipeline and a strong financial position, we remain confident in the future prospects for GW," the company said.

Source - Pharma Times

www.bbc.co.uk 26 May 2010

Assessments under new benefits system investigated

A BBC Scotland investigation finds that tens of thousands of claimants who are genuinely sick or disabled may have been refused the new Employment Support Allowance.

BBC Scotland investigations correspondent Mark Daly has been examining how the system works in practice.

It was heralded by government in 2008 as the answer to the nation's sick note mentality. Employment Support Allowance was brought in to replace the creaking incapacity benefit system and was designed to help a million people back into employment.

The tough new medical assessment would tackle the something for nothing culture: weeding out cheats and scroungers, whilst those who really needed help, would receive it.

But fast forward just a year and a half, and there are calls for the planned roll-out of ESA to be shelved.

For the past three months, BBC Scotland has been investigating allegations that tens of thousands of genuinely sick or disabled people have been denied the benefits they're entitled to.

Under pressure

One of the first people I met was David McNeish, 34, from South Queensferry. He'd been a successful political lobbyist. But last year, his life began to crumble under the strain. A bout of depression escalated and he was diagnosed with acute psychosis, and assessed as a danger to himself and others.

He said: "It was kind of like a car crash, to be honest - it just came out of the blue. From me going from being, you know, a very capable, very competent person to suddenly seeing things that weren't there, hearing voices, not really being able to function properly at all."

David applied for ESA, and was sent for the medical, known as the Work Capability Assessment, which is designed to assess what a claimant can do, as opposed to what they can't.

ESA is based on a points system and is divided into three groups:

- The support group, which means you are so ill you are unlikely to be able to work - which pays almost £97 a week
- The work-related activity group, which means you have the potential to work and will get support back into employment, and this pays £91 a week
- Fit for work category, which means you are not entitled to ESA and must find a job, or apply for jobseekers allowance, which pays £65 a week.

Claimants must score 15 points or more to qualify for ESA, and after providing evidence of his mental health problems, David was sure he would qualify, and was shocked to find he hadn't.

He said: "It was a real shock when we got the letter through to say that I'd been assessed as fit to work, and it was even more of a shock to find out that we'd been awarded zero points, which just seemed completely inconceivable, given what was going on.

"I've been working all my life, I've never not been working, and I felt I needed a lot of help for a short period of time, and I didn't get it. And what I did get, I had to fight for."

'Tougher than expected'

I went to meet Dr Chris Johnstone, a GP from Paisley who'd piloted a back to work scheme at his practice. He agrees with the principle of ESA, but has serious concerns about the medical. He said: "The problem that the patients are reporting back to me appears to be that the medicals don't appear to be thorough. They don't appear to cover the areas that the patients want to talk about, often mental health problems, and a lot of people who I would have thought are clearly unfit for work, or possibly suitable for further training, are just being deemed fit for work."

The medical was always anticipated to be much tougher than under the previous incapacity benefit regime but the reality has taken even the government by surprise and has found more than two-thirds of sickness claimants fit for work. That's almost 20% more than the DWP had anticipated. And this has been reflected in the number of appeals.

Our Freedom of Information request revealed that ESA appeals are running at about 8,000 hearings a month, which is double the number of the next most commonly appealed benefit, Disability Living Allowance. About 40% of those ESA claimants who do appeal have their decisions reversed.

Professor Paul Gregg was commissioned by the government to design a key element of ESA, the part which provides support for people back into the workplace, and he has serious concerns.

He said: "I think the DWP are surprised at how few people are passing this new test and moving onto ESA."

"I'm concerned in a sense that too many of the people who the system I was designing for are not entering that space and potentially not benefiting from it."

www.mstrust.org.uk 2 June 2010

Stem cell therapies for inflammatory brain diseases now possible

A team of investigators from the University of California in Irvine (UCI) Sue & Bill Gross Stem Cell Research Center have recently made important strides in the field of using stem cells as therapies for mitigating the effects of injuries on the central nervous systems.

The investigators managed to discover the mechanisms employed by adult neural stem cells, as they navigate through the human brain to the site of injuries, in order to fix the damages. This is the final piece to a puzzle that, once completely solved, could allow researchers to create new, stem cell-based therapies for inflammatory diseases of the brain, such as, for instance, multiple sclerosis (MS).

According to Center investigators Tom Lane and Kevin Carbajal, the leaders of the research effort, the answer to the riddle laid within the actions of the immune system. Details of their study appear in this week's early online issue of the esteemed scientific publication Proceedings of the National Academy of Sciences (PNAS). The experts believe that the new knowledge, which also includes details about how transplanted stem cells get targeted to the location where they are needed, could help inform bioengineers in developing new stem cell therapies aimed directly at neurological diseases whose main trait is inflammation. Multiple sclerosis is the most notorious example in this sense.

"Previously, we've seen that adult neural stem cells injected into the spinal column knew, amazingly, exactly where to go. We wanted to find what directed them to the right injury spots," says Lane, who is also the Chancellor's Fellow, and a UCI professor of molecular biology and biochemistry. "In this study, we've taken an important step by showing the navigational cues in an inflammatory environment like MS that guide stem cells. Hopefully, these cues can be incorporated into stem cell-based treatments to enhance their ability to repair injury," the expert adds.

In previous studies that Lane and his team conducted, it was demonstrated that therapies based on adult neural stem cells were able to improve motor functions in mice with chronic MS symptoms. This is why the group believes that the new work could have far-reaching implications for human patients as well. Given the new knowledge, it may be safe to hypothesize that using adult stem cells, and knowing how to target them to where they need to go, may help human MS patients as well. Lane is the recent recipient of a Collaborative MS Research Center Award from the National Multiple Sclerosis Society

[Source - Softpedia](#)

www.mstrust.org.uk 12 May 2010

EU agency prepares to assess first stem cell drug

The first regenerative medicine based on stem cells could be filed for approval in Europe later this year, bringing the groundbreaking medical technology a step closer to reality.

The European Medicines Agency (EMA) said on Wednesday it had been informed about the "intent of a European manufacturer to submit the first application for marketing authorization for a stem cell-based product."

Drugmakers typically send a letter of intent to the London-based watchdog four to six months before a formal application, a spokeswoman said, so this would imply a filing toward the end of 2010.

The EMEA declined to name the company involved. In preparation for the first of a possible wave of applications, officials from the EMEA met this week with drug company officials, regulators from the United States and Japan, and academic scientists to discuss guidelines for approving such treatments.

Research into stem cells has increased dramatically in recent years and there are currently some 40 clinical trials underway in the European Union exploring the use of stem cells to regenerate lost or damaged tissues and tackle various cancers. The majority use adult mesenchymal stem cells.

Stem cells -- which are particularly flexible when taken from days-old embryos -- are the body's master cells and can potentially be used to repair the heart, spinal cord, liver, pancreas, eyes and other parts of the body.

But their use is controversial and involves risk -- notably the danger that foreign cells might be rejected or could proliferate uncontrollably, leading to tumors.

Managing risks

To address some of these issues, the EMEA has drafted a "reflection paper" on the process for approving stem cell-based therapies, which will be finalized by the end of 2010.

"Stem cells hold the promise of an unlimited source of cells for therapeutic applications to treat patients who have no or only unsatisfactory treatment options," said Christian Schneider, chairman of the agency's Committee for Advanced Therapies.

"However, these therapies bear certain risks, such as tumourgenicity and immunorejection, and hence need to be carefully regulated with the input from multi-disciplinary expertise."

For many investors, stem cells remain off the radar screen for now after early excitement about the science was followed by delays and disappointments in the clinic.

But companies pioneering the technology have not given up and a growing number of large pharmaceutical companies are also starting to dip their toes in the water.

Believers see a parallel between the evolution of stem cell treatment and monoclonal antibodies. Antibody technology was first developed in the 1970s but it is only recently that such drugs have become blockbusters.

Among listed companies, Britain's ReNeuron is about to start the world's first stroke trial using foetal stem cells, while US-based Geron hopes to restart a study using embryonic cells to treat spinal cord injuries in the third quarter of 2010.

Any stem cell treatment filed with the EMEA later this year could, in theory, become commercially in 2011.

The agency's scientific committee has instructions to issue an opinion within 210 days of receiving an application, or 120 days in the case of an accelerated procedure, although this regulatory clock can be stopped if more information is needed.

Source - [Reuters](#)

www.mssociety.org.uk 26 May 2010

MS Societies' work around vitamin D highlighted in Lancet Neurology

A news article in the latest edition of The Lancet Neurology highlights the potential for vitamin D supplements as a reasonable prevention strategy for MS and mentions the MS Societies' work around vitamin D.

The story highlights the award-winning Shine on Scotland campaign and the international summit on vitamin D and MS, which MS Society Scotland will be hosting in September.

Leading researchers from around the world will be coming to Scotland for the summit and discussing the latest evidence surrounding the role that vitamin D might play in a variety of public health issues and will be making recommendations to the Scottish Parliament.

Multiple hopes for Multiple Sclerosis

Anette Hansson, is one of the tens of thousands that fall prey to MS across Europe, she describes the onset of the disease:

“I had a lot of balance problems. My muscles were very weak. I had pain in my eyes. It was the optic nerve, I understood afterwards. So I went to the doctor. And after a while I got the diagnosis.”

Claudio Conforti is an MS sufferer in Italy:

“The neurologist told me: ‘Listen. Stay calm, but magnetic resonance has confirmed that you have multiple sclerosis.’”

Anette Hansson:

“My first reaction was to see a wheelchair in front of me. I think you usually react that way with multiple sclerosis; a wheelchair is what the disease is about, I thought then.”

Francesco Sinibaldi is another who has been hit by MS:

“I feel good. I work, I can walk, I have a wife, two kids. I have a fairly normal life. But in the back of my mind there is always this slight... this slight uncertainty.”

From the streets and gardens of Rome to the hospital rooms in Stockholm the reality of MS stalks Europe, but what is it?

Multiple Sclerosis affects the ability of nerve cells in the brain and spinal cord to communicate with each other.

Severe cases result in permanent disability.

Francesca Aloisi is the coordinator of the Neuropromise project researching the disease:

“There are two parallel processes in this disease. First there is an inflammatory process, which is chronic and stays in the patients for life. At the same time, there is a second process, a neurodegenerative process, when patients lose different components of their central nervous systems. This neurodegeneration is very likely linked to the inflammatory process.”

Researchers at the Italian Institute of Health

coordinate a European Union Research project aimed at developing new therapeutic Strategies to treat patients.

Biologists first had to get a better understanding of the complex mechanisms behind the development of the disease.

Molecular analyses of damaged tissues confirmed that inflammation of the nervous system somehow sparks the neurodegenerative process.

Roberta Magliozzi is a biologist at the Italian Institute of Health:

“We can for instance analyse lesions inside plaques of the central nervous system of patients. We can not only confirm the existence of those lesions, but also their extension. And we can somehow establish how those lesions are connected to the presence of cells from the inflammatory system.”

Researchers now have a clearer idea of how the disease evolves.

But they are still unsure how it emerges, and why it affects some people while sparing others.

Francesca Aloisi:

“We still don’t know what causes this disease. What we do know is that genes and environment interact in a complex way in the development of MS.”

At the Karolinska Institute in Sweden, genetic studies have been performed to further understand the causes of the disease.

Laboratory experiments were combined with clinical studies of volunteers like Anette.

Now in her 50s, this former stewardess was diagnosed with MS 2005.

Anette Hansson:

"I'm doing now the same things that I used to do. But differently. I'm not running any more; I'm walking with my sticks. I'm not dancing ballet as I used to do; I'm doing yoga."

The research helped to identify some genes thought to be linked to the disease's origin.

Tomas Olsson is Professor of Neurology at the Karolinska Institute:

"We have found at least 5 new risky genes for Multiple Sclerosis. One at a time, each gene affects the risk of developing the disease a little. But as a whole, they point to a disease pathway. And this information can provide new ideas for finding new targets for therapy."

Tomas Olsson then combined that genetic data with different lifestyle and environmental patterns.

And he came to certain conclusions.

"There have been three main suspects regarding lifestyle and environmental factors that can help the disease to develop. First is lack of sun exposure and the resulting carencia of Vitamin D. Second is the infection by a virus, called Epstein-Barr virus. And the third is smoking.

The link between smoking and multiple sclerosis is a recent finding. Here in Sweden we have compiled and published the largest research material in Europe on this topic. Our studies show that smoking increases the risk of Multiple Sclerosis by around 60 %. But together with two different risk genes for MS, smoking can increase the risk by 2500 %."

Breakthroughs in biology, genetics and environment have helped researchers to focus on new treatments against neurodegeneration.

But not necessarily new drugs.

As Lars Faggar Professor of Neuroimmunology at the University of Oxford explains:

"Clearly there is a big need to develop new drugs to help the patients. The problem is however that it costs approximately one billion euros and 10 to 15 years of hard work to develop these new drugs. So one might wonder if it is possible to take a shortcut. And that's what we have tried to do. We have been trying to see if a drug that was used many many years ago in Europe to treat hypertension ~~that's increased blood pressure~~ could also be used to stop neurodegeneration. What we have shown in our model systems is that yes, to a certain extent, this drug stops neurodegeneration."

A joint European research effort with a final aim: to corner a still elusive disease.

Claudio Conforti MS sufferer:

"Our expectation is that Science will provide soon some specific results. If not for us, long-term Multiple Sclerosis patients, at least for younger sufferers."

Tomas Olsson:

"As far as MS research was concerned, 25 years ago you had to tell the patient: come back when you are worst. Then 15 years ago we got some treatments that reduced the number of relapses by some 30 percent. And now there are certain treatments that may decrease the relapses by some 60 or 70 percent."

Francesco Sinibaldi MS sufferer:

"I don't expect that researchers will be able to find from one day to the other a miracle cure for all patients. It is a complex disease. But for sure they will...little by little find solutions for some of us."

Tomas Olsson:

"So the challenge for us researchers now is to understand the causes and the pathogenesis of the disease much better, so that in fifteen years we have much more precise therapies."

Anette Hansson MS sufferer:

"I feel very good. And I have met a lot of people with Multiple Sclerosis who also feel good. So this disease does not mean that you will be stuck to a wheelchair. And even if you end in a wheelchair, that is not the end of the life. I really feel I have a very good life now."

DISCLAIMER

Articles in this Bulletin are meant for the sole purpose of information only and do not necessarily reflect the views of the committee.

YOUR JOKES

DON'T YOU JUST LOVE OLD PEOPLE?

A farmer stopped by the local mechanic shop to have his truck fixed. They couldn't do it while he waited, so he said he didn't live far and would just walk home. On the way home he stopped at the hardware store and bought a bucket and a gallon of paint. He then stopped by the feed store and picked up a couple of chickens and a goose. However, struggling outside the store he now had a problem - how to carry his entire purchases home. While he was scratching his head he was approached by a little old lady who told him she was lost.

She asked, 'Can you tell me how to get to 1603 Mockingbird Lane ?'

The farmer said, 'Well, as a matter of fact, my farm is very close to that house.

I would walk you there but I can't carry this lot.'

The old lady suggested, 'Why don't you put the can of paint in the bucket.

Carry the bucket in one hand; put a chicken under each arm and carry the goose in your other hand?'

'Why thank you very much,' he said and proceeded to walk the old girl home.

On the way he says 'Let's take my short cut and go down this alley. We'll be there in no time.'

The little old lady looked him over cautiously then said, 'I am a lonely widow without a husband to defend me. How do I know that when we get in the alley you won't hold me up against the wall, pull up my skirt, and have your way with me?'

The farmer said, 'Holy smokes lady! I'm carrying a bucket, a gallon of paint, two chickens, and a goose. How in the world could I possibly hold you up against the wall and do that?'

The old lady replied, 'Set the goose down, cover him with the bucket, put the paint on top of the bucket, and I'll hold the chickens .'

An elderly couple, Margaret and Bert, moved to Texas .

Bert always wanted a pair of authentic cowboy boots, so, seeing some on sale, he bought them and wore them home.

Walking proudly, he sauntered into the kitchen and said to his wife, 'Notice anything different about me?'

Margaret looked him over. 'Nope.'

Frustrated, Bert stormed off into the bathroom, undressed and walked back into the kitchen completely naked except for the boots.

Again he asked Margaret, a little louder this time, 'Notice anything different NOW?'

Margaret looked up and exclaimed, 'Bert, what's different? It's hanging down today, it was hanging down yesterday, it'll be hanging down again tomorrow!'

Furious, Bert yelled, 'AND DO YOU KNOW WHY IT'S HANGING DOWN, MARGARET?'

'Nope', she replied.

'IT'S HANGING DOWN, BECAUSE IT'S LOOKING AT MY NEW BOOTS!!!!'

Without changing her expression, Margaret replied, 'Shoulda bought a hat, Bert. Shoulda bought a hat.'

MEMBERS COMPETITION

A £5 prize will be given to the member whose entry has the most correct answers. Even if you do not know all the questions, send in those you have answered – you could still win!

- 1/ Which musical instrument did Jacqueline Du Prey play?
- 2/ What name did Gerry Dorsey adopt?
- 3/ Who was killed by an IRA bomb in the underground car park of the House of Commons?
- 4/ Who succeeded William Wordsworth as Poet Laureate?
- 5/ In 1965 who had 'That Loving Feeling'?
- 6/ What is the collective noun for a group of caterpillars on the move?
- 7/ Which city was the setting for George Orwell's 1984?

Name:

Address:

Send Completed Forms To:
Mr D Henderson
74 Windermere Road
Stockton-on-Tees
TS18 4LY

All entries to be received by the next social. The winner will be drawn from all entries received with the highest number of correct answers.

Answers to last quiz:

1/ Halifax 2/ Sunderland 3/ Stirling Moss 4/ Wellington 5/ The Tempest 6/ Lancaster
7/ Blenheim 8/ Hurricane or Typhoon

Connection: All World War 2 Aeroplanes