

My prog-MS ezine

For people with progressive MS and those interested in it

Issue number 17, January/February 2018

Welcome to issue 17 of my ezine about progressive MS and MS progression. My name is Ian Cook. I'm a secondary progressive MSer from Birmingham, UK.

In this issue are six pages of news plus two features about issues that matter to prog-MSers. In news there's a story about an unexpected setback for licensing biotin and a story about ocrelizumab the primary progressive medication which is gradually mounting the regulatory hurdles necessary for it to be licensed.

There are two features. One on pages 4-5 looks at the surprising theory that aluminium may be involved in MS and its progression. The other feature on pages 8 and 9 looks at ten drugs and treatments which are in development and where we may hope for progress in 2018.

If there is any story you would like me to follow then I'm at iancookjournalist@yahoo.co.uk

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Biotin licence application unexpectedly withdrawn

A licence application to the European Medicines Agency (EMA) for high dose Biotin to be used as a treatment for secondary progressive MS (SPMS) has been withdrawn by pharmaceutical firm Medday.

The EMA has been examining data on biotin since September 2016, but in November last year its Committee for Medicinal Products for Human Use (CHMP) concluded that the clinical data from two trials of 253 patients was not sufficient to assess the effectiveness or safety of the high dose biotin medicine (MD1003, Qizenday.) Medday, the company behind MD1003/ quizinday, have reserved the right to re-apply for licensing in the future.

In a press notice the EMA said its Committee for Medicinal Products for Human Use (CMPH) considered the data on the medicine's effectiveness was not robust enough, and said there were uncertainties regarding its safety given the small number of patients treated with high dose biotin (MD1003/Qizenday). In addition the CMPH said that more information was needed about how the medicine is absorbed, modified and removed from the body.

Although the decision not to apply for a licence comes as a surprise there had been questions asked about the way in which biotin actually works. Biotin (Vitamin B7) is part of the B-complex group of vitamins and found in various foods including eggs and almonds. It helps the body convert food into fuel, and also helps the nervous system function properly. One theory about its use in MS is that biotin activates enzymes involved in cell growth and myelin synthesis and enhances energy production in demyelinated nerves.

Prof. Gavin Giovannoni of Barts Hospital in London interpreted the recent events in the following way: " The problem I see for this agent is they they don't really know how it works and this may be a fundamental problem. The trials have been designed to show that it is an agent targeting progressive disease, but based on the early reports it suggested to me that the benefit was either symptomatic or perhaps repair and so the trial design may need to be very different. Why do I say this? It was because the reported benefits were occurring quickly."

Despite this setback there is still hope for biotin as Medday say they plan to continue with the ongoing phase 3 clinical trial which is looking at the superiority of MD1003/Qizinday over placebo (dummy pill) in the disability of 600 patients suffering from progressive multiple sclerosis especially those with difficulty walking. This trial is due to report in 2019

More details of all stories on p14

Ocrelizumab closer to approval as PPMS treatment

Roche, the makers of ocrelizumab (Ocrevus) have announced that the US Committee for Medicinal Products for Human Use (CHMP) has given a "positive opinion" for use of the drug in adults with primary progressive MS (PPMS). A top UK researcher says this is "great news".

The positive CHMP opinion is based on data from a Phase III study (ORATORIO) in which the drug significantly slowed disability progression and reduced signs of disease activity in the brain (MRI lesions) compared with placebo when tested over an average of three years.

'The positive opinion on ocrelizumab is great news for people in the UK with MS who are now one step closer to having this important new treatment option,' said Professor Gavin Giovannoni, Chair of Neurology at Barts and The London School of Medicine and Dentistry. 'Controlling clinical and sub-clinical disease activity as early as possible is an important treatment goal for people living with MS. The clinical trial data demonstrate that ocrelizumab consistently impacts disease progression .'

Ocrelizumab has already been licensed for use in countries across North America, South America, the Middle East, Eastern Europe, as well as in Australia and Switzerland. Based on this positive CHMP opinion, a final decision from the European Commission regarding the licence of ocrelizumab is expected in the coming months. Following a positive European Commission decision, ocrelizumab will then be granted marketing authorisation that will be valid across the European Economic Area member states. The drug is taken as an intravenous infusion every six months.

Anti-coagulant blocker aids remyelination in mouse trial

Protamine — a drug which stops the blood thinning effects of heparin which is used to treat deep vein thrombosis — was seen to trigger remyelination in mice with myelin damage.

While pointing a way forward for studies of myelin regeneration in multiple sclerosis (MS), the research team investigating protamine and remyelination say protamine may not be an ideal candidate for human MS trials because of its side effects. Nevertheless they said their research might lead to the discovery of similar compounds with properties better suited to human use.

For further details of all news stories go to page 14



Does aluminium play a role in MS progresssion?

As a sceptic I normally avoid off beat-theories about the cause of MS - particularly theories that involve metal toxicity and things like mercury fillings and lead pipes. But one theory caught my interest recently. It was about aluminium and its possible role in MS.

For more than 10 years scientists at Keele University led by Prof. Chris Exley have explored a possible link between the two. And their research has demonstrated that people with MS have an unusually high "burden" of aluminium in their bodies. The scientists also found MSers, particularly those with secondary progressive MS (SPMS), excrete significant amounts of aluminium in their urine . All this has made them wonder if aluminium might have a role to play in my MS and its progression.

In their research the scientists noted in animal models of aluminium intoxication, myelin is a preferred target for aluminium in the brain. And of course myelin breakdown is a factor in the progression of MS in humans. This and other known facts about aluminium, such as the fact it can play a role in the breakdown of the blood brain barrier led Exley in 2015 to advance the hypothesis that human exposure to aluminium played a part in MS and that perhaps aluminium was the environmental factor that has long been acknowledged as part of the MS disease process.

So, in the same year Exley and his fellow scientists at Keele designed a small clinical trial to test the theory and included in their trial a possible therapeutic element. The scientists had previously shown that regular drinking of a silicon-rich mineral water was an effective and non-invasive therapy for removal of aluminium from the body. They wondered whether it would also be effective in helping remove aluminium from the body of individuals with MS

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A 24 week trial was completed towards the end of 2015 and the results are now reported in the journal EBioMedicine. During the trial's first 12 weeks (designated the control period) urinary excretion of aluminium and silicon in 15 individuals with SPMS (Secondary progressive MS) was measured.

For the next 12 weeks those on the trial drank at least 1litre of a silicon-rich mineral water every day and urinary excretion of aluminium and silicon continued to be measured. The authors say the results of their trial are unequivocal both in demonstrating that individuals with SPMS have a high body burden of aluminium and that regular drinking of silicon rich mineral water helps to remove aluminium from their body.

The scientists are refreshingly honest in admitting that the trial period (24 weeks) is too short to know if the people with SPMS actually benefitted from drinking the silicon-rich mineral water and clearly far more work needs to be done to prove that aluminium is the environmental factor involved in MS and its progression. However, if you are looking for a cheap and harmless way to test out the theory all you have to do is avoid aluminium foil, cans and throw away those aluminium pots and pans, oh and drink silicon rich mineral water such as Volvic, (a massive 32mg silica per litre) See below.



For more details of all news and features go to page 14

Nerve protecting drug to be tested in progressive MS

A US based pharmaceutical company has received $316,384 in grants to see if a nerve cell-protecting drug, already tested in Parkinson's Disease, can work in progressive MS.

Longevity Biotech's drug LBT-3627 aims to protect and repair damaged nerve cells and restore balance to the immune system in patients with Parkinson's Disease – a neurodegenerative disorder. Longevity will now use the grant given by the US National MS Society to see if LBT-3627 can also protect nerve cells in animal models of progressive MS.

"These preclinical [trial] studies may provide evidence for further development of LBT-3627 for progressive forms of MS." said Dr. Mark Allegretta, associate vice president of commercial research at the National MS Society. "LBT-3627 has neuroprotective qualities, and part of this work will determine its ability to promote maturation of myelin-producing cells."

Studies in animal models of Parkinson's disease showed that LBT-3627 protects up to 80 percent of dopamine-producing nerve cells from damage. Dopamine is a nerve-cell signalling transmitter. An initial analysis suggested that LBT-3627 works in part by regulating certain immune cells' response to inflammation. These cells, known as microglia, reside in the brain and are believed to be also involved in the MS disease process.

Dr. Jenell Smith, Longevity's lead scientist on the project said: "We hope that we can provide a desperately needed novel therapeutic paradigm to treat neurodegenerative disorders such as MS."

New research gives more clues to gut bacteria's role in MS

US researchers have found that mice engineered to have immune system-related genes that help make people susceptible to MS only developed MS-like disease if gut bacteria were present, and were most likely to get the disease in adolescence or young adulthood, rather than later adulthood. The researchers from Rutgers Robert Wood Johnson Medical School also identified the biological "pathways" by which gut bacteria triggered disease-causing immune activity.

This study adds evidence to the potential role that intestinal bacteria play in the brain inflammation that underlies MS, and sheds light on how bacteria may interact with other possible risk factors.

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Non-psychoactive cannabis drug could treat spasticity

Results of a new study into cannabidiol (CBD) – the non-psycho-active part of the cannabis plant – have shown that CBD pills can potentially treat spasticity in MS.

The study "Single-Dose Pharmacokinetics of Oral Cannabidiol Following Administration of PTL101: A New Formulation Based on Gelatin Matrix Pellets Technology" was published in the journal Clinical Pharmacology in Drug Development.

The primary goal of the study was to assess the safety, pharmacokinetics (how a drug is absorbed, distributed and expelled) and tolerability of a single dose of a cannabidiol product PTL101. Effects were compared to Sativex - a mouth spray based on CBD plus another compound from the cannabis plant, the psycho-active delta-9-tetrahydrocannabinol (THC).

The PTL101 trial was conducted by PhytoTech Therapeutics (PTL) in Israel using a delivery system used to create PTL101 beads containing organically derived and pharmaceutical-grade CBD. PhytoTech Therapeutics was working with Satipharm, a subsidiary of Harvest One, a global cannabis company based in Canada focused both on the medical and recreational cannabis markets.

CBD is the main non-psychoactive component of the cannabis plant, and it has been associated with neuroprotective, anti-inflammatory, anti-seizure, anxiolytic, antidepressant, and antipsychotic effects. Several studies have reported that cannabis-derived therapeutic products can be of benefit to patients with MS.

US research may lead to novel drug treatment for progressive MS

Scientists have uncovered two closely related cytokines — molecules involved in cell communication and movement — that may explain why some people develop progressive multiple sclerosis (MS), the most severe form of the disease.

They identified a cytokine, called macrophage migration inhibitory factor (MIF), along with its related protein, D-dopachrome tautomerase (D-DT), which are associated with progressive MS. The findings, authored by researchers at Yale University, Oregon Health & Science University, and the University of California may point the way toward developing a novel treatment to prevent and treat progressive forms of the disease. There are now approved therapies, as well as new ones in development in the Oregon and Yale labs, which target the MIF pathway and could be directed toward progressive MS.

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Ten drug and treatment trials that may be game-changers for progressive MS in 2018

2018 has the promise to see drugs being licensed to treat progressive MS. With just one drug Ocrelizumab close to being licensed for primary progressive MS, progressive MSers are awaiting more drug treatments particularly for secondary progressives. Here are my top ten developments to watch out for in 2018.

1. Siponimod

Siponimod (also known as BAF312) is a tablet being developed for secondary progressive MS by Novartis Pharmaceuticals. currently in Phase 3 trials. It works in a similar way to fingolimod trapping immune cells (B and T cells) in the body's lymph nodes. This stops them getting into the brain and spinal cord, where they cause damage to the myelin coating around nerves.

A trial called EXPAND took place involving 1,651 people with secondary progressive MS and top line results from the trial were announced in September 2016. Siponimod reduced risk of disability progression by 21% compared with placebo (dummy drug) . Siponimod also reduced brain shrinkage.

In 2016 Norvatis, who developed siponimod, announced they will finish analysing the results and publish them in a scientific journal. They are also planning to consult with health authorities on the next steps for this treatment. For siponimod to be available to people with secondary progressive MS, the phase 3 trials results will need to be submitted to the European Medicines Agency for licensing. Hopefully that will happen early in 2018.

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2. Bone marrow cell treatment for chronic multiple sclerosis

A trial - Assessment of bone marrow-derived cellular therapy in progressive multiple sclerosis (ACTiMuS) is taking place in Bristol, UK, led by Professor Neil Scolding.

The bone marrow is a rich source of various types of stem cells which could potentially repair and protect nerve cells in the brain and spinal cord in MS and the two year Bristol study involves 80 people with primary or secondary progressive MS. Stem cells are being collected from participants' bone marrow and then reintroduced by infusion. Researchers will look for changes in nerve conduction inside the brain and spinal cord. Trial results are expected in 2018.

3. Ibudilast

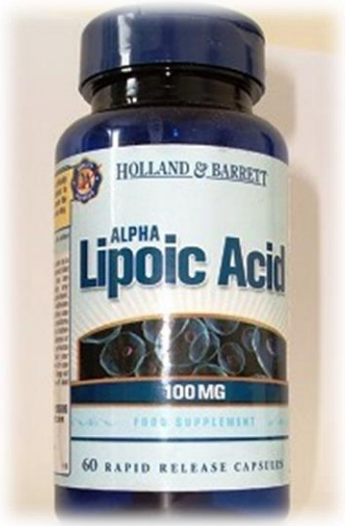
Ibudilast (known as MN-166) is being developed for progressive MS by pharmaceutical firm MediciNova. The drug is currently in phase 2 clinical trials and is thought to have anti-inflammatory effects and to protect against cell death, which may be beneficial in MS in reducing nerve cell loss. Ibudilast is taken as a pill. A phase 2 trial of 250 people with primary and secondary progressive MS. showed the drug significantly reduced brain shrinkage (atrophy) compared with placebo. Ibudilast still needs to go through larger phase 3 trials to fully test its effectiveness in progressive MS before it can be licensed. But in March 2016 the US Food and Drug Administration (FDA), responsible for licensing drugs in the US, granted ibudilast “fast track status”. This is designed to speed up the development of new treatments and will enable MediciNova to meet the FDA more frequently and submit applications for review earlier. Expect some news here in 2018

4. Riluzole

Riluzole is a tablet already used to treat motor neurone disease (MND). It is being tested as a treatment for secondary progressive MS in a mid-stage phase 2 clinical trial.

Riluzole works by stopping a chemical called glutamate interacting with nerve cells. It is known that a build-up of glutamate can damage nerve fibres, and researchers believe that blocking glutamate could help to protect nerves in MS. Riluzole is part of MS-SMART, a phase 2 trial that will test the potential of three different drugs - riluzole, amiloride and fluoxetine– in 440 people with secondary progressive MS. The trial is due to finish in 2018.

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5 Lipoic acid

Lipoic acid (left) also known as alpha lipoic acid is an organic compound found in small amounts in kidney, heart, liver, spinach, broccoli, and yeast extract. A capsule containing high doses of lipoic acid is being developed for secondary progressive MS, and is currently in phase 2 clinical trials. Lipoic acid is also widely available in smaller amounts as an over-the-counter supplement.

Studies in animal models of MS have shown that lipoic acid may alter the behaviour of certain immune cells, preventing them from entering the central nervous system. If correct, this could stop the immune cells from attacking and damaging myelin. Research has also suggested that lipoic acid could also help to protect nerves from damage and offer neuroprotection. Results of a phase 2/3 trial found that treatment with lipoic acid reduced brain shrinkage by 68% compared with placebo, but there was no significant difference in disability scores. A phase 3 trial is being planned.

6. Masitinib

Masitinib (AB1010) is a tablet being developed for primary and secondary progressive MS by AB Science. It's currently in a phase 3 trial. Masitinib is thought to block some of the body's inflammatory responses, which could suppress the immune attacks that occur in MS. A phase 3 trial is testing if masitinib can improve mobility, hand/arm coordination and cognitive function in progressive MS The trial is involving 600 people with primary progressive or relapse-free secondary progressive MS. In March 2017 AB Science announced that masitinib has passed a "non-futility" test, which suggests it has shown signs of being effective. Based on this, the Independent Data Safety Monitoring Committee (IDMC), an independent group of experts who monitor data while a clinical trial is ongoing, recommended that the study continues. Results are expected in 2018. A licence could then be sought.

7. Fluoxetine (Prozac)

Fluoxetine (Prozac) is being tested in a phase 2 clinical trial called MS-SMART in people with secondary progressive MS. Researchers think the drug could be neuroprotective.MS-SMART is a three year trial testing three different drugs - fluoxetine, amiloride and riluzole – against a placebo treatment in 440 people with secondary progressive MS. The trial is expected to be completed in 2018.

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8. Simvastatin

Simvastatin is a tablet (see above) used to treat high cholesterol, but has also shown promise in MS. It's being tested in a phase 3 clinical trial to treat secondary progressive MS.

In an earlier trial of 140 people with secondary progressive MS two doses of simvastatin were compared with a placebo (dummy) drug. Researchers found that people taking high dose simvastatin had reduced brain shrinkage and better end of study disability scores compared with those taking placebo. Results were published in the Lancet in March 2014. A phase 3 trial is now monitoring simvastatin in a much larger number of people with MS. The trial will take six years to complete. Results are expected in 2023**,** but hopes are high.

9. Rituximab

Rituximab (also known as Rituxan or Mabthera) is already licensed to treat some lymphomas, and is being tested as a treatment for progressive MS. Rituxumab is an antibody therapy that targets immune cells called B cells, thought to contribute to myelin damage in MS. It is taken by Intravenous infusion. A phase 2/3 study is currently comparing the benefits of rituximab with the licensed treatment Copaxone in 60 people with active progressive MS. The trial is due to finish in 2018.

10. Amiloride

Amiloride is a tablet already used to treat heart disease. It's being tested for people with secondary progressive MS in a phase 2 clinical trial called MS-SMART which is also testing two other drugs – fluoxetine and riluzole. The drug is a sodium channel blocker. A build-up of sodium in the brain is thought to be linked to nerve damage in MS, and scientists predict that amiloride could protect nerves by stopping sodium entering cells. The trial is expected to be completed in 2018. **For details of all news stories and features go to page 14**

Could a fungus be linked to MS and its progression?

Two researchers writing in the journal Frontiers of Neurology have speculated that a fungal infection may be linked to MS. In a free to read article they argue that many aspects of MS are consistent with fungal infections.

The researchers say the low risk of MS during childhood and a "moderate association" with herpes simplex virus type 2 (genital herpes) suggest genital exposure to microbes (including fungi) should be investigated as a possible MS trigger and that many lines of evidence are consistent with a fungal role in the illness. Future microbiome and serological studies should consider fungi as a possible risk factor for MS, they say.

They also note that though fungal infections have not been widely studied in MS, dimethyl fumarate (DMF), first used as an industrial fungicide, was recently repurposed to reduce MS symptoms. Future clinical studies should consider the effect of fungicides other than DMF on MS symptoms, they add.

Increased epilepsy risk identified in MS

There is a direct link between the presence and severity of MS and the risk of epilepsy, according to study findings published in Neurology.

Investigators obtained patient data from the Swedish MS register and compared these patients with age- and sex-matched controls. The rate of epilepsy was 3.5% in the MS group compared to 1.4% in the control group.

Looking at subgroups of the people with MS researchers found the epilepsy rate was much higher (5.5%) in Progressive MS compared to the Relapsing Remitting MS group (2.2%). Longer disease duration and more disability (higher EDSS ratings) were also both associated with an increased risk of epilepsy.

Commenting on the findings in his blog http://multiple-sclerosis-research.blogspot.com/ neurologist Prof Gavin Giovannoni said: This study shows clearly that pwMS are at a higher risk of epilepsy than age and sex-matched controls. The strong association between risk of epilepsy and both disease duration and EDSS implies that the effect is related to disease activity. I imagine that atrophy and focal lesions both drive the increased risk of seizures. Additionally, chronic inflammation itself may lead to alterations in brain networks which predispose to seizures independently of causing degeneration of focal lesions.

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Trial of new PPMS drug fails, but some promising results

A once-daily tablet that targets neurodegeneration and inflammation using a "novel mechanism of action" has failed to deliver improvements in symptoms of primary-progressive MS (PPMS). However, patients who took the drug did show a reduction in new T2 brain lesions.

Those are the main findings of ARPEGGIO, a phase II study investigating the effect of 48 weeks treatment with laquinimod on brain volume changes in 375 people with primary progressive MS carried out by pharmaceutical company Active Biotech. In a press release published in December 2017 Active Biotech, said data from the trial will be presented at a future scientific conference where full results will be published. Of particular interest to those with PPMS will be the reduction in new T2 lesions. The number of T2 lesions is thought to be a good indication of the burden of MS disease over the prior year.

Laquinimod 's novel mechanism of action is based on affecting the levels of certain cytokines (substances released by immune cells) and reducing the passage of immune cells into the brain and spinal cord. Laboratory investigations suggested this might have both neuroprotective and anti-inflammatory action in MS. As we went to press there was no news of any further investigations involving the drug.

Lifetime cancer risk lower in MS patients

People with MS have a lower overall lifetime risk of cancer relative to a general population matched by area, age, sex and habits like tobacco use and alcohol consumption. New research suggests this lesser risk might be due to the nature of MS itself or to disease modifying therapies used by patients.

Researchers at the Université Clermont Auvergne, in France, conducted a case-control study by self-administered questionnaire; in total, 1107 responses were used for the analysis. The same survey was also given to 1,568 healthy people, serving as controls, in the Auvergne region. Age, gender, and history of smoking and alcohol use were taken into account.

Results showed that 7.32 percent of MS patients had been treated for cancer, whereas cancer affected 12.63 percent of those in the control group. Statistical analysis found that MS patients were 37 percent less likely to develop cancer compared to the control group — and neither DMT use, including immunosuppressants, nor disease course appeared to increase cancer risk among patients. The study, "Decreased prevalence of cancer in patients with multiple sclerosis: A case-control study," was published in the journal PLOS ONE.

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In the next (March-April) edition

As Spring arrives I go cyling on a quadracycle, a trike, and a recumbent



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