

My prog-MS ezine

For people with progressive MS and other interested people

Issue number 20, July/August 2018

Hello and welcome to the latest edition of my free ezine about progressive MS and MS progression in general. My name is Ian Cook. I'm a secondary progressive MSer who lives in Birmingham, UK.

In this issue are nine pages of important prog-MS news stories plus two features about issues that matter to prog-MSers. The first feature on page 5 is one I originally wrote in 2016 about cooling aids and other ways to beat the Summer heat, but the current UK weather seemed to make me want to send it out again. In the second feature on page 10 I discuss a theory about MS and anti-retroviral drugs – something that I think has real promise for all Msers and is gaining traction. Read the feature and you'll see why.

IN THIS ISSUE



Feature

Cooling jackets and other ways to beat the heat this summer

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- **NICE shock over Ocrevus refusal, p2**
- **Research shows stem cells work in SPMS, p7**

Shock as NICE issues initial refusal for Ocrevus as primary progressive treatment

The National Institute for Health and Care Excellence, (NICE) has decided against recommending Ocrevus (ocrelizumab) as a publicly funded treatment for adults with primary progressive MS (PPMS). The decision was made at an initial assessment in June.

NICE decisions are based on the results of a cost-effectiveness assessment. According to NICE, Ocrevus (ocrelizumab, developed by Genentech) did not meet "value for money" criteria as a cost effective PPMS treatment in the NHS, although the evaluation committee agreed Ocrevus is a "step change" for these patients.

Studies have shown that Ocrevus can slow disease progression in patients with PPMS, found in about 14 percent of all MS patients, and may even delay a patient's need for a wheelchair for up to seven years, and can cause a 25 percent reduction in disease progression in patients with PPMS.

Clearly this evidence was not felt not strong enough to justify approval. The price of the drug, which sells in the U.S. at an estimated annual list price of $65,000 may have been a factor in the decision. The NICE appraisal committee will meet again on 2 August to review comments received about the decision and further manufacturer evidence. NICE expects to publish its final decision for the NHS in October 2018

In June, NICE reversed an earlier decision regarding relapsing-remitting MSers (RRMS), and recommended Ocrevus be included in the NHS for this group. The reversal was made after Genentech, part of the Roche group, worked with NICE to reach agreement on an undisclosed price for the infusion treatment.

Ocrevus is a humanized monoclonal antibody against a specific immune cell – CD20 positive B lymphocytes – that play a crucial role in myelin and nerve cell damage. It suppresses the immune system and dampens inflammation. It was approved by the European Commission in January 2018 to treat both relapsing remitting MS (RRMS) and PPMS, making it the first approved PPMS treatment in Europe. The U.S. Food and Drug Administration approved Ocrevus to treat both MS forms in March 2017. Canada, Australia, Switzerland and countries in the Middle East and South America followed.

For details of sources for all news stories go to page 15

New drug approvals for prog-MS imminent, report suggests

Despite problems in gaining NICE approval for primary progressive MS, Genentech's drug Ocrevus (ocrelizumab) has led to a sea change in the treatment of progressive forms of the illness, leading to an increased interest in other disease-modifying therapies (DMTs) a new report says.

Now, other potential treatment choices for progressive MS forms are likely to become available including Novartis' investigative tablet siponimod (BAF312).

MedDay Pharmaceuticals' MD-1003, (based on vitamin B7 – biotin) and AB Science's masitinib as well as existing treatments, such as Genzyme's Lemtrada (alemtuzumab) Merck KGaA's (known as EMD Serono in the U.S. and Canada) Mavenclad (cladribine), could also be used in progressive MS according to the report from Spherix Global Insights.

As previously reported and now confirmed in the updated Spherix report, the number of neurologists prescribing Ocrevus as a first-line treatment for PPMS has stabilised and is expected to remain so for the foreseeable future. Neurologists treating progressive MS and looking for alternatives to Ocrevus will most likely choose from the biotin (vitamin B7) based MD-1003, from MedDay Pharmaceuticals, or masitinib, being developed by AB Science.

According to the Spherix report, patients with active SPMS will most likely continue with DMTs, at least until the anticipated launch of siponimod. Novartis is planning to soon file a marketing application requesting siponimod approval with the U.S. Food and Drug Administration. A similar filing in Europe is expected later this year. If siponimod is approved, it will likely increase the number of active SPMS patients receiving a DMT treatment. For patients with non-active SPMS, the use of DMTs, including that of Ocrevus, has remained low. The report also highlights that only two out of five neurologists anticipate siponimod use in not-active SPMS patients, although efficacy data in this subgroup of patients will be necessary to result in a significant increase in rates of treatment.

Regarding masitinib, currently in development for PPMS and relapse-free SPMS, the report suggests that data on not-active SPMS could potentially increase the drug's financial coverage and be an incentive for trials in this sub-group of patients.

For details of sources for all news stories go to page 15

Roche announce new primary progressive study of Ocrevus

Despite the NICE situation pharmaceutical company Roche has announced a new phase III trial of its primary progressive MS drug Ocrevus (Ocrelizumab).

The trial called ORATORIO-HAND will be novel in that recruitment will extend beyond EDSS 6.0 up to EDSS 8.0, i.e. wheelchair users. The primary outcome will be the 9-hole peg test which measures upper limb function rather than the more usual 25 foot timed walk test which measures lower limb (leg) function.

According to Prof. Gavin Giovannoni, of Barts Hospital in London and principal investigator of the new study, the announcement of the ORATORIO-HAND trial represents a milestone in the history of MS. “It challenges the dogma that once you have more advanced MS (progressive disease) that you are 'irredeemable' and sends a message of hope to all people with MS in wheelchairs that we haven't forgotten you”.

Mood and anxiety disorders linked to disability progression in MS

New research has shown that mood disorders, including depression, anxiety and bipolar disorder are linked to increased disability levels in women with MS. The research adds to the knowledge that some people with MS who live with additional diseases can experience worse disability outcomes.

Published in the journal Neurology, the study looked at a research team, based in British Columbia and Nova Scotia in Canada who followed more than 2,300 people with MS. Participants were followed over an average of ten and a half years and their hospital records were examined to determine whether they had mood or anxiety disorders. In particular the team focused on people with MS who had depression, anxiety and bipolar disorder.

During the ten years, close to 36% of people in the study experienced one of the mood disorders. Women who had a mood disorder in addition to their MS had higher levels of MS-related disability, though the same relationship was not seen in men with MS. This work on psychiatric disorders in MS, along with previous research investigating physical conditions in addition to MS, highlights the need for people with MS and their medical teams to ensure that all medical conditions are adequately managed. In this case, suitable management of mood disorders such as depression, anxiety and bipolar disorder would also assist with the disability outcomes in MS. **For details of all news stories go to page 15**



My top tips for keeping cool this very hot summer

The days may be long, but the weather is too hot, yes summer can be hell when you have progressive MS.

The reason is of course heat. Demyelinated nerves are poor conductors of electrical signals and their performance gets worse when your body's core temperature goes up by just half a degree centigrade.

Clearly the best solution is to avoid the heat but this isn't always possible, so I have prepared my top five cooling products

1.Cooling vests (See above) The sleeveless zip-up jacket shown above is my tried and trusted version of the Kool Max Zipper Vest (KMVZ). It comes with water-based cooling packs which you freeze before putting into special pockets sewn into the jacket lining. Cooling packs can be re-frozen and re-used over and over again. I have been the proud owner of one of these cooling vests for around five years and yes, it really has made a difference. Some cooling vests have special cooling crystals rather than ice packs and with these you simply soak the cooling vest in cold water for a couple of minutes and the cooling crystals hold the cold temperature for a long time.

2. Cooling scarves and towels. These are an alternative to a cooling vests. Many are made from material that retains water, allowing the water to evaporate slowly leaving you colder as a result. When the towel dries out you just re-wet it and within minutes it's cool again. As well as cooling scarves and towels there are also cooling ties, scarves, neck wraps and hats which can also double up as sun hats.

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3. A cool pillow. If your summer heat problem is a night-time one and you find yourself suffering "hot pillow syndrome" a cool pillow could be the answer. The Chillow Plus (left) is a personal cooling pad which can be used with your existing pillow. You fill it up with tap water which is absorbed into the foam core. You can either insert the Chillow Plus into your pillow or sleep straight on it for maximum coolness. It isn't just a fantastic way to keep cool at night, you can also use it during the daytime as a cool cushion.

4. Fans. I am a big fan of fans. Most people think of big electric fans for the office but don't underestimate the cooling effect that you can get from the hand held variety. These are portable, cheap and devastatingly effective when used with the cooling sprays.



5. Cooling sprays. These amazing aerosol sprays are sold widely at chemists, are easy to carry and unbelievably effective. You might think they are a waste of money and plant sprayers are just as good but cooling sprays really are the perfect way to chill out quickly. They have been described as air conditioning in a can, and the secret is the super-fine spray which is incredibly refreshing.

Finally, if you are planning to go to a hot country this summer then remember that some of the best ways to keep cool are actually the cheapest. Soaking your feet in cool water, putting your hands under the cold tap, taking a cool shower, wearing a hat outdoors, even putting ice cubes in your cold drinks, can help.

For details of all products go to page 15

Stem cells could treat secondary progressive MS

Fat-derived stem cells are a safe and feasible treatment for patients with secondary progressive multiple sclerosis, a Phase 1/2 clinical trial carried out in Spain shows.

The trial, "Adipose-derived mesenchymal stem cells (AdMSC) for the treatment of secondary-progressive multiple sclerosis (SPMS): A triple blinded, placebo controlled, randomized phase I/II safety and feasibility study," was published in the journal PLOS One, and can be viewed freely. See references section.

Adipose (fat) derived stem cells (AdMSCs) can be acquired through a minimally invasive procedure called a lipectomy — a surgical procedure to remove body fat. In the Phase 1/2 clinical trial (NCT01056471) researchers set out to determine the safety and feasibility of treating SPMS patients with two different doses of AdMSCs in a Phase 1/2 clinical trial

Researchers first obtained the AdMSCs through a lipectomy where fatty tissue is surgically removed from under the skin. Then, 30 of the patients received either a single infusion of placebo, low-dose AdMSCs or high-dose ADMSCs and were followed for 12 months. In total, 11 patients were given placebo, 10 were given low-dose, and nine were given high-dose AdMSCs.

Although the study was not designed to determine the efficacy of AdMSCs, some hint of efficacy was observed by the use of MRI and evoked potentials. Larger studies would be needed to investigate the potential therapeutic benefit of the technique," the researchers said.

For details of sources for all news stories go to page 15

Potential myelin repair treatment starts clinical trial – prog MSers may be included at future date

Bexarotene, a drug that could help the brain re-grow myelin in people with MS, has started a phase II clinical trial.

Researchers at Cambridge Centre for Myelin Repair and Edinburgh Centre for MS Research have discovered that Bexarorene, which is already a licensed cancer treatment, might help people with MS. Working together they showed that parts of the brain affected by Bexarotene are also responsible for encouraging myelin repair.

Participants in the trial take several capsules (which might be bexarotene or a placebo) a day for 6 months and remyelination is assessed by one MRI scan at the beginning of this six-month period and one at the end. The trial centres are at Cambridge and Edinburgh.

Although the trial is only for people with relapsing remitting MS there are hopes that it will be extended to people with progressive MS at phase 3, if the phase 2 trial is successful. Writing in the website MS research blogspot Professor Alasdair Coles, who is leading the trial explained why progressive MSers have been excluded from the trial. He said: "I understand why we are being challenged to include people with progressive MS. But there is a good scientific reason. We know the side-effects of this drug in cancer patients are quite significant... and we do not want to expose people unnecessarily to those risks, especially as we do not know whether the drug works at all. But, if the trial is positive, and the drug is reasonably safe, we will certainly suggest a trial in progressive MS. We are hoping to recruit 50 people for this trial, and we are half way there. If we can recruit the final 25 quickly, we will have a result by the end of next year, from which everyone will benefit."

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Decision on legal medical cannabis expected soon

The Government has revealed it will decide whether to legalise cannabis for medical use in the next few months or even weeks.

Home Secretary Sajid Javid ordered an evidence review of the drug after the well publicised recent case of six year old Alfie, who has a genetic condition which causes him to have clusters of seizures unresponsive to almost all medications. His mother took Alfie to Holland and discovered that three drops of cannabis oil per day significantly reduced the number of seizures. After a month of campaigning Alfie was granted a licence to be treated with the drug.

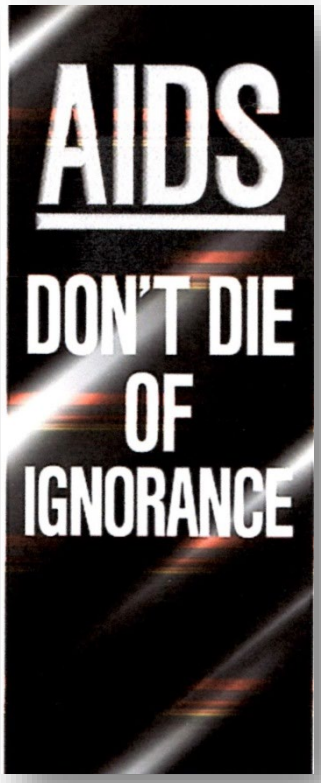
Cannabis is known for its therapeutic qualities, which can help relieve a number of symptoms experienced by many people diagnosed with MS. Professor Dame Sally Davies, Chief Medical Officer for England and Chief Medical Advisor to the UK Government, specifically notes that there is moderate to conclusive evidence that the use of cannabis improves symptoms of spasticity and sleep disturbance in MS patients.

In the first part of the evidence review Prof. Davies recommended that medical cannabis should be moved out of Schedule one, a group of drugs which are not legal and cannot be prescribed. This is the first time that a Government official has formally acknowledged that cannabis has medical benefits.

In the review she said: As Schedule one drugs by definition have little or no therapeutic potential it is clear that from a scientific point of view keeping cannabis based medicinal products in Schedule one is very difficult to defend. I therefore recommend that the whole class of cannabis based medicinal products be moved out of Schedule one."

Moving these drugs out of Schedule one would allow them to be prescribed under controlled conditions by registered practitioners for medical benefit. It would also allow the evidence base on the therapeutic benefits associated with using this class of drugs to be improved through research, maximising benefits to patients. In 2013 Sativex the mouth spray containing two cannabinoids (the chemicals which give cannabis its medical properties) was moved from Schedule 1 to the less restrictive Schedule 4 of the 2001 Misuse of Drugs Regulations effectively distinguishing it from cannabis in other forms such as the cannabis oil used by Alfie which is still in the most restrictive Schedule 1 under the 2001 regulatations.

For further information on news stories go to page 15



Does this 1980s AIDS poster have a message for us MSers?

Are we dying of ignorance about retroviruses and MS?

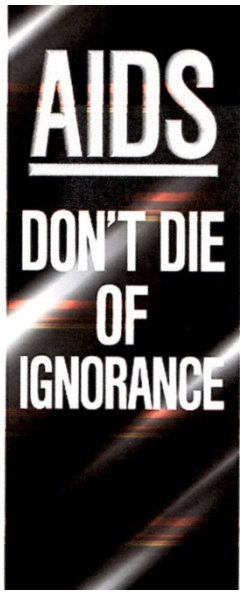
For some time I have wondered if anti-retroviral drugs could hold the answer to MS. My curiosity goes back to 1986 when I was working as a reporter for a weekly social work magazine. At the time I was writing about a social workers' project in San Francisco helping disabled gay men struck down with an unknown virus that was at the time deadly.

While I was writing the story the deadly virus was identified and given a scientific name. Initially the virus, or retrovirus to be accurate, was called htlv-3 (later renamed HIV). As a journalist I explained what "htlv 3" stood for, and what htlv-1and 2 were. The letters "htlv" stand for Human T Lymphotropic Virus. And for personal reasons I was more interested in htlv 1 and 2 than htlv 3 (HIV/AIDS).

The reason for my personal interest was that in 1986 I was being investigated for MS which is a demyelinating disease. And while writing the San Francisco story I discovered that infection with htlv1 and 2, which exists mainly in the tropics, could cause a demyelinating disease known as TSP/HAM (Tropical Spastic Paraparesis/ Human Acquired Myelopathy which has a strong resemblance to MS. I personally think it's like tropical MS.

At the time I felt the subject was interesting but I didn't know what link if any there was between retroviruses, htlv 1,2, 3 and MS . Then a few years later at an MS conference I was approached by an MS doctor who had earlier in his career worked with AIDS patients. He told me that people with AIDS almost never get MS. Once again I wasn't sure what to make of this but there did seem to be a growing although vague connection between MS and retroviruses.

Continued on page 11



Ctd from page 10 Fast forward 25 years to around 2010 and things were no longer so vague. Research carried out in Denmark had shown that the AIDS doctor was right, HIV and MS are very rarely found together. Also two anti-retroviral drugs were about to be tested on MS. One drug, raltegravir, was to be tested in London. The other drug GNbAC1 was being tested in Switzerland where trials are continuing. What exactly anti-retroviral drugs are targeting in MS is unclear and the link between MS, viruses and retroviruses is still being unravelled.

Over the past decade I have read occasional reports of people with MS who claim improvement after taking anti-retroviral AIDS drugs. An academic paper published in 2011 claimed an Australian MSer took a cocktail of AIDS drugs and all his symptoms totally disappeared. A similar story was published on the BBC News website in 2015 about a Brighton woman MSer. Earlier this year another academic paper published in the US said more or less the same thing. This 2018 paper described how an American woman with MS who took an AIDS drug called Combivir showed "significant disease improvement" in her MS.

Over the years there have been a series of possible explanations for how antiretroviral drugs might work in MS. The first is that anti-retrovirals stop an "endogenous" or inherited retrovirus that sits in our DNA and is passed down the generations from coming back to life and causing MS in the right circumstances.

A second theory is that anti-retroviral drugs stop the DNA of the Epstein Barr virus (EBV) from copying itself , something that conventional anti-virals are apparently unable to do. The authors of the 2018 paper believe the second theory. Their paper is titled "Could anti-retrovirals be treating EBV in MS? – a case report". I think the question is rhetorical.

My 30 year interest continues and for some time I have wondered whether I could persuade any doctor to prescribe me an antiretroviral drug like combivir, but I have given up on the idea as I don't have HIV/AIDS However I know there is a drug called PrEP (Pre-Exposure prophylaxis) which contains similar medications to AIDS drugs like Combivir and which can be prescribed privately to HIV negative men who feel their lifestyle puts them in danger of contracting AIDS. It just requires a visit to a private GP and his agreement to prescribe it, plus the expense of a few hundred pounds. But would it help me and is it worth it? Like everything in MS it's hard to know – there are only questions, no answers and in progressive MS there's precious little time to find the answers. What should I do?

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News

Chemical that Stimulates Oestrogen Promotes Myelin Repair in Mouse MS

A chemical compound called indazole chloride promotes repair of myelin, the protective layer of nerve fibers, through "beneficial" inflammation in a mouse model of MS, a study reports.

The preclinical research, "Increase in chemokine CXCL1 by ERβ ligand treatment is a key mediator in promoting axon myelination," was published in the journal Proceedings of the National Academy of Sciences.

In the brain and spinal cord, myelin is formed by cells called oligodendrocytes after they mature from precursor cells. In contrast to healthy individuals, whose nervous system is able to regenerate damaged myelin, patients with MS cannot and such damage is permanent.

Prior work in mice with MS has shown that indazole chloride, a synthetic chemical that binds to and stimulates the oestrogen receptor ERβ, improves motor function, promotes remyelination, and eases inflammation.

Now, scientists at University of California, Riverside have found that indazole chloride's effect on remyelination correlates with increased levels of CXCL1 in the periphery and in astrocytes, a cell of the central nervous system (CNS).

CXCL1 is a type of small molecule called a cytokine with a key role in inflammation. It binds to CXCR2 in oligodendrocytes, and as such is implicated in myelination. The investigators also observed that extensive remyelination was accompanied by immune cells accumulating in the CNS.

While inflammation is damaging in autoimmune diseases, the researchers noted it can also be beneficial — inflammation is required to fight infections and speed wound healing. Their findings suggest that indazole chloride promotes "good" inflammation, protecting oligodendrocytes while they remyelinate.

The US scientists consider indazole chloride an attractive compound because it does not cause the side effects of oestrogen therapy.

For further details of all news stories go to page 15

New 'epigenetic' drug starts trial for prog MSers

A new drug which treats the interaction of genetic and environmental (epigenetic) components of MS is undergoing clinical trials in Spain. ORY-2001 has been developed by Oryzon Genomics which is currently recruiting MS patients including those with progressive MS for Phase 2 clinical trials.

ORY-2001 is classified as an epigenetic therapy, meaning it moderates the expression of genes without altering their DNA sequence. The therapy works by targeting and inhibiting, in a selective manner, the activity of two enzymes: lysine (K)-specific demethylase 1A (LSD1) and monoamine oxidase B inhibitor (MAOB).

LSD1 (also known as KDM1A) is an epigenetic modulator, meaning it regulates the expression of several genes by removing epigenetic marks that sit on top of the genes and "switches them" on and off. It is hoped that by blocking LSD1 activity, ORY-2001 can modify gene expression. MAOB plays an important role in the breakdown of neurotransmitters, or chemical messengers, like dopamine.ORY-2001 was previously shown to reduce cognitive impairment and neuroinflammation in pre-clinical animal models of MS, including in mouse MS — the experimental autoimmune encephalomyelitis (EAE) model.

In a Phase 1 clinical trial with healthy volunteers, ORY-2001 was found safe and capable of effectively reaching the brain. Based on these positive results, Oryzon has launched its Phase 2a SATEEN clinical trial to test ORY-2001 in patients with relapsing-remitting and secondary progressive MS. The trial is ongoing at nine sites across Spain, and is currently enrolling patients. Participants will be randomized to receive two doses of ORY-2001, administered by mouth, or to a placebo group. The trial's main objective is to evaluate the safety and tolerability of the two doses of ORY-2001 compared to placebo. Additional (secondary) objectives include the effect of ORY-2001 on inflammation compared to placebo controls, measured by magnetic resonance imaging (MRI).

Doubts over value of high intensity exercise in progressive MS

An analysis of several studies of High Intensity Interval Training (HIIT) for people with MS has found that although it benefits people with low levels of disability it is less effective with progressive MS especially more severe levels of disability (Extended Disability Status Scale 6.0-8.0). High Intensity Interval Training (HIIT) involves short bursts of high intensity exercise. These "bursts" typically last 20min of 4-6 cycles of maximal effort lasting 1-4min with rests between the "bursts". Compared to continuous moderate intensity training, HIIT is better at improving VO2 max (the maximum amount of oxygen that a person can use during high intensity workout. **For details of all news stories go to page 15**

Study says Rituximab is effective for younger progressive MSers

Rituximab, an antibody that targets a protein found on the surface of immune B-cells involved in MS development, could be both effective and safe as a treatment for some progressive MS patients.

That is the finding of a Swiss study "Effectiveness and safety of Rituximab in multiple sclerosis: an observational study from Southern Switzerland," published in the journal PLOS One.

The benefits for people with progressive MS (PMS) were found particularly among younger patients with evidence of inflammatory activity on MRI (magnetic resonance imaging) scans. Rituximab has already been found to be generally safe and effective in treating relapsing remitting MS— with comparable effectiveness to Tysabri (natalizumab) and is sometimes used "off label".

In the Swiss study 82 patients — 42 with relapsing-remitting MS (RRMS) and 39 with progressive MS (PMS) were treated with at least one rituximab infusion between September 2009 and February 2018. Patients were followed for an average of 1.5 years, with results finding no evidence of disease activity in 80% of all rituximab-treated MS patients (59 people). Three PMS patients experienced "minor" relapses during this time, the study said.

Side effects, mostly recurrent respiratory tract and urinary infections, were reported in 24 patients, and were most often found in progressive MS patients. These led to six people discontinuing rituximab treatment.

"This study provides additional evidence for the use of rituximab in MS, with a potential benefit also in progressive cases," the researchers wrote. Rituximab, they concluded "could represent an additional effective, relatively cheap and safe therapy in the panel of existing MS treatments," although "clinicians must be vigilant for the potential occurrence of infections.

Sold as Rituxan in the U.S. and MabThera in Europe, the drug is used to treat diseases that include certain non-Hodgkin's lymphomas and chronic lymphocytic leukaemia.

For details all news stories go to page 15

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Page 2

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Page 3

New drug approvals imminent

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page 4 Oratorio-HAND trial story

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Page 4 Mood story

Source: https://www.msif.org/news/2018/04/26/mood-and-anxiety-disorders-linked-to-disability-progression-in-ms/

pages 5-6 Feature on cooling products

1. The Cooling Vest KMVZ as shown :

2016 Price = £106.95 (including delivery to most areas of the UK).

Availability - most sizes in stock but not all colours in all sizes. A fresh delivery is awaited. For details go to http://peakpersonalcooling.uk/

2 The Chillow Plus . Go to **http://www.personalcooling.co.uk/** for details of a range of cooling products including Chillow Plus .

page 7 stem cells story

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Anti-retrovirals feature

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Page 13 Exercise story

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