

My prog-MS ezine

For people with progressive MS and other interested people

Issue number 43, May/June 2022

Hello and welcome to the slightly later than usual edition of my ezine about progressive Multiple Sclerosis and MS progression in general. My name is Ian Cook. I'm a secondary progressive MSer from Birmingham, UK. I'm 63.

In this issue are eight pages of prog-MS news stories. There are also two features. One on page 5 is about exercise and the suggestion that it could actually clow down MS progression – interesting theory and one you can try out yourself at home.

There's also a feature on the present research on Epstein Barr virus and MS where I ask whether my own childhood brush with the virus paved the way for my first MS symptoms ten years later. See page 10 for details.

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News

Late-stage trials test new drug for EBV infected B-cells

US bio-pharma Atara Biotherapeutics plans to launch two Phase 3 clinical trials of its investigational immunotherapy ATA188 which targets EBV infected bone marrow (B) cells in people with non-active, progressive forms of MS.

The trials will go forward, once positive results from an interim analysis of the Phase 2 portion of the EMBOLD trial (NCT03283826), are delivered. These results are expected in the coming months. Interim findings will inform the optimal size needed for EMBOLD — currently enrolling progressive MS patients at U.S. and Australian sites — to meet its goals.

While MS is thought to be caused by a combination of genetic and environmental factors, a growing body of evidence points to Epstein-Barr virus (EBV) infection as its leading cause. EBV infects about 95% of the adult population at some point in life. After infection — which can go unnoticed by most people — the virus lingers in the body in a dormant form inside B-cells, a type of immune cell involved in the abnormal immune attacks that drive neurodegeneration in MS. Therapies aiming to clear EBV from the body could potentially help lessen MS symptoms and may even pave the way for a treatment or even a cure.

Infused directly into the bloodstream, ATA188 is made of T-cells — immune cells with the ability to fight infections and other threats — modified to target and kill EBV-infected B-cells. The two-part, Phase 1/2 EMBOLD trial is evaluating ATA188's safety and effectiveness in adults with non-active PPMS and SPMS. Newly presented EMBOLD data, concerning up to 3.5 years of follow-up, indicated that 20 (83.3%) of the 24 patients experienced a sustained stabilization (13 patients) or improvement (seven patients) meaning a lessening in their functional disability, as assessed with the Expanded Disability Status Scale (EDSS).

Up to 80 PPMS and SPMS patients with evidence of past or current EBV infection are currently being enrolled in EMBOLD's Phase 2 part. They will be randomly assigned to two cycles of either the optimal dose of ATA188 or a placebo. After one year of follow-up, patients in the placebo group will receive two cycles of ATA188, while those originally assigned to the therapy will be given one cycle of the therapy and one cycle of placebo,. After these, Phase 2 participants may choose to enrol in an open-label extension study, and be treated once a year for up to three years.

Atara is also planning Phase 2 trials of ATA188 in other MS patient populations, including clinically isolated syndrome, relapsing-remitting MS, and active progressive MS.

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Prog MS Trial Finds Repeat Bone Marrow Infusion Is Safe And Feasible

Repeat harvesting of bone marrow cells and infusing them back into the bloodstream is safe and feasible in people with active progressive MS according to data from a small, UK based proof-of-concept clinical trial.

The study is called "Repeat infusion of autologous bone marrow cells in progressive multiple sclerosis — a phase I extension study (SIAMMS II),"and is published in the magazine Multiple Sclerosis and Related Disorders.

The bone marrow is home to the stem cells that give rise to blood cells and immune cells. An emerging body of research has shown that these cells have immune-modulating and repair-promoting properties that may help to lessen or repair damage caused by MS.

In a preliminary Phase 1 clinical trial called SIAMMS, six people with progressive MS had a procedure where cells were harvested from their bone marrow, and then infused into the bloodstream that same day. A years' worth of follow-up data showed that the procedure was generally well-tolerated, and measures of disability and disease activity were largely stable or showed improvement.

A Phase 2 clinical trial called ACTiMuS (NCT01815632), sponsored by North Bristol NHS Trust, is comparing this procedure against a placebo treatment in 80 people with progressive MS. ACTiMuS will address the question of whether a single infusion of autologous [off-the-self] bone marrow cells helps in progressive MS. Theoretically, repeated treatments with the procedure might give additional benefits.

To learn more, scientists in the U.K. conducted an extension study, dubbed SIAMMS II (NCT01932593). It enrolled four progressive MS patients who had undergone the original procedure in the SIAMMS study. In SIAMMS II, they underwent the procedure for a second time. The goal was to assess the safety and feasibility of repeating the procedure, and results were positive, with the repeated procedure being generally well-tolerated by all four participants. An average of over 7.2 years had elapsed since the original SIAMMS study and all four patients had experienced notable disease progression during that period, the researchers wrote.

Over a year of follow-up in SIAMMS II, measures of disability that included walking function, hand dexterity, and cognitive function, as well as nerve function, remained largely unchanged. No new or actively inflamed brain lesions were evident in the participants. The result "demonstrates proof-of-concept that repeated bone marrow-derived cell therapy is feasible in patients with progressive MS," the scientists concluded

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Eight More SPMS Patients Cleared for New Nose Spray Treatment

The U.S. Food and Drug Administration (FDA) has approved starting Foralumab treatment in up to eight MS patients under a special access programme based on findings from the first two secondary progressive MS (SPMS) patients given foralumab nasal spray, an experimental therapy which damps down inflammation of a type of cell in the brain.

Foralumab nasal spray comprises a novel physiological approach to induce disease-modifying benefits in the CNS [central nervous system; the brain and spinal cord] by dampening microglial inflammation. Microglial cells — the CNS' own immune cells — are the immune cells of the central nervous system and consequently play important roles in brain infections and inflammation. These cells have been implicated in the abnormal inflammatory and immune responses that drive neurodegeneration in MS.

"The first validation of our innovative approach came from our recently reported results showing positive clinical benefits and microglial modulation in a patient with secondary progressive multiple sclerosis who was treated for six months with nasal foralumab," a researcher said.

The new access program is expected to provide additional data to assess the robustness of clinical responses to treatment. Its main goals are to determine foralumab's safety and tolerability, while additional goals include clinical and immune responses.

Notably, the first patient given foralumab was experiencing continuous disease worsening, with a clear decline in walking abilities over the previous two years. According to previously reported data, six months of treatment with foralumab nasal spray were generally well-tolerated and resulted in improvements in the patient's walking ability, finger dexterity, and cognitive function. Foralumab data now provide, for the first time, strong evidence of a link between lesser microglial activation and clinical gains in SPMS patients.

Foralumab is an antibody designed to suppress inflammatory and immune responses by targeting the CD3 receptor protein on the surface of T-cells, a type of immune cell involved in the abnormal immune attacks that drive nerve cell death in MS. Notably, the therapy was previously found to not only reduce the activity of inflammatory T-cells, but also to increase that of regulatory T-cells, which work by dampening the inflammatory activity of other immune cells.

Administered directly into the nostrils, foralumab nasal spray is expected to act more locally so to have a more favourable safety profile than conventional antibody-based treatments, which are administered into the bloodstream. **For details of all stories go to page 13**



Could exercise be a treatment for my "smouldering MS"?

One of the problems of my MS progressing is that I do less, if any, exercise. The simple reason is that I feel less able to exercise.

I have often wondered whether I have entered a sort of vicious circle where lack of exercise leads to faster progression which in turn leads to less exercise. I think you get the general idea.

I was therefore fascinated to read about Professor Gavin Giovannoni of Barts Hospital in London and his study of exercise as a treatment for smouldering MS. If lack of exercise is driving progression then exercising more might, in theory, stop or even reverse that progression. Prof. Giovannoni puts it better than I do. So, over to you Prof G. He says the following:

"It is clear that running or exercise, in general, is one of the most underutilised treatments we have for multiple sclerosis and neurodegeneration in general. It is clear, at least for me, that exercise and diet have to be at the base of any brain health pyramid. As always there is biology that underpins the treatment effects of these simple lifestyle interventions.

"Most of us have assumed exercise works by simply stimulating growth factors and endorphins in the central nervous system. Growth factors are responsible for anti-ageing and endorphins for the mood-elevating effects of exercise and explain the runner's high. But the science may be more complex than that.

"Recent work shows that the health benefits of exercise on ageing may be mediated by a hormone glycosylphosphatidylinositol (GPI)-specific phospholipase D1 (Gpld1), which is released from the liver increases after exercise and has been shown to correlate with improved cognitive function in aged laboratory mice (Horowitz et al. Science. 2020 Jul 10;369(6500):167-173.).

"A recent review shows that in people with MS (pwMS) exercise increases blood levels of brain-derived neurotrophic factor (BDNF) (Shobeiri et al. PLoS One. 2022 Mar 3;17(3):e0264557.). Other studies have shown that BDNF is linked to recovery mechanisms and neuroprotection in MS**. Continued on page 14**

Continued from page 5 "A recently published study in pwMS examined acute exercise (single-bout) and training effects of high-intensity interval training (HIIT) compared to standard exercise therapy i.e. moderate continuous training (MCT) (Joisten et al. Neurol Neuroimmunol Neuroinflamm. 2021 Mar 29;8(3):e982.).

"Remarkably, acute exercise reduced peripheral blood neurofilament levels (pNFL) and increased neuroprotective blood metabolites, whilst reducing markers of inflammation. Importantly, changes in neurofilament levels correlated positively with the anti-inflammatory effects of exercise measured in the blood. All of these studies and others support the case for studying exercises effects on MS in more detail," he said.

What Prof G is proposing is a study involving high-intensity interval training (HIIT) comparing it to low-intensity exercise (LIE). All study subjects will have metabolic profiling, lumbar puncture for CSF analyses, muscle biopsies for ageing markers and physical and cognitive assessments. The primary outcome will be CSF biomarkers of smouldering MS including neurofilament levels, a panel of inflammatory and ageing markers. It is also proposed to look at metabolic and muscle ageing profiles and physical & cognitive outcomes.

Personally speaking I know not all study proposals end up in actual studies and I am a little sceptical given that I can't see who would pay for such a trial. Generally speaking it's only drugs companies who fork out for these trials and given that this trial isn't a drugs trial I guess Prof G will be reliant on another income stream and I can only think of charities and wealthy philanthropic benefactors as possible supporters of this work.

That said there is nothing stopping me (and you) trying out High Intensity Interval training (HIIT)over the next three months and see whether it improves my and your condition. We have nothing to lose and much to gain. I am putting on my trainers as I write these words. Do the same and watch this space, as they say.

More information on page 14

Glatiramer Acetate gets US patent for treating prog-MS

Leading bio-tech Mapi Pharma has been granted a U.S. patent covering the use of GA Depot, a long-acting preparation of glatiramer acetate (GA) for treating primary and secondary progressive MS

The U.S. Patent and Trademark Office patent, No. 11,167,003, is titled, “Methods for suppressing or alleviating primary or secondary progressive multiple sclerosis (PPMS or SPMS) using sustained release glatiramer depot systems.”

It covers ways “of administering or implanting a depot formulation comprising glatiramer salts,” including GA Depot, in treating progressive forms of MS — which include primary progressive MS (PPMS) and secondary progressive MS (SPMS) — and grants Mapi exclusive use of GA Depot until March 25, 2038.Mapi has applied for similar patents elsewhere, including in the European Union, Canada, and Japan.

Glatiramer acetate (sold as Copaxone, with generics also available) is an approved disease-modifying therapy for adults with relapsing MS, administered as an under-the-skin injection every day or three times a week. GA Depot is designed to be a longer-acting, sustained release version of glatiramer acetate, administered via a single intramuscular (into-the-muscle) injection once every four weeks. As such, it intends to be more convenient and to improve patient adherence to the therapy. In previous Phase 2 trials, GA Depot was reported to safely slow disability progression for up to three years in people with relapsing-remitting MS (RRMS) and PPMS.

These findings led the company to launch a global Phase 3 trial (NCT04121221) into the effectiveness, safety and tolerability of one year of monthly GA Depot injections versus a placebo in up to 1,016 adults with active SPMS, relapsing forms of MS, or those with clinically isolated syndrome.

Its primary goal was to determine if GA Depot, given as 40 mg intramuscular injections, significantly lowered the annual relapse rate compared with placebo after one year of treatment. Secondary measures included changes in brain lesion number and total brain volume. Interim trial results, presented at the American Academy of Neurology 2022 Annual Meeting in April demonstrated that GA Depot was generally safe and that EDSS scores remained stable throughout the study, with no evidence of confirmed disability progression in patients. Dexterity and walking abilities also remained stable. Four patients exhibited new or enlarging brain lesions, and three had inflammatory brain lesions.

Mapi announced that is looking for a partner to support Phase 3 studies of GA Depot in treating PPMS and to possibly co-market the treatment. **For details of all news stories go to page 14**

News

Majority of prog MSers on Ocrevus show “no progression”

Nearly three of every four participants in the CONSONANCE clinical trial evaluating Ocrevus (ocrelizumab) in people with primary or secondary progressive MS showed no evidence of disease progression after a year of treatment.

That’s according to new data presented at the American Academy of Neurology (AAN) 2022 Annual Meeting, which took place in the US in April. The presentation was titled “A multicentre, open label, single-arm, phase 3b study (CONSONANCE) to assess the effectiveness and safety of ocrelizumab in patients with primary and secondary progressive multiple sclerosis: year-1 interim analysis.”

Ocrevus is a B-cell-depleting medication developed by Genentech, a member of the Roche Group. It is approved in the U.S. to treat relapsing forms of MS — including clinically isolated syndrome, relapsing-remitting MS (RRMS), and active secondary progressive MS (SPMS) — primary progressive multiple sclerosis (PPMS). Bio-pharma Roche is sponsoring an open-label Phase 3 clinical trial called CONSONANCE (NCT03523858) that is evaluating the safety and effectiveness of Ocrevus in 900 people with progressive forms of MS (PPMS or SPMS). The trial is actively recruiting participants at more than 130 locations around the world.

The presentation covered data for 629 participants — 325 with SPMS and 304 with PPMS — who were treated with a standard regimen of Ocrevus for one year. Researchers assessed the segment of participants with no evidence of disease progression (NEP). Results showed that 74.9% of the patients achieved NEP after one year on Ocrevus — 78.2% of those with SPMS, and 71.3% of the PPMS patients. The team also assessed the proportion of patients with no evidence of progression or disease activity (NEPAD), defined as NEP plus no disease relapses and no new or worsening brain lesions. A total of 58.7% achieved NEPAD after one year of treatment, including 58.9% of patients with SPMS and 58.4% of those with PPMS. Among patients who did experience disease progression, the main drivers of progression were worsening by 20% or more in walking ability (16% of participants) and/or new or enlarging brain lesions (19% of participants).

A separate presentation at AAN assessed cognitive outcomes in the CONSONANCE trial, specifically the Symbol Digit Modalities Test (SDMT), a general measure of cognitive ability, and the Brief Visuospatial Memory Test-Revised (BVMT-R), which assesses problems with memory and visual/spatial reasoning. Results showed that after a year on Ocrevus, the average score on the SDMT increased by 10.7%, while the average score on the BVMT-R increased by 14.9%. **For details of all news stories go to page 14**

PIPE-307, Aiming to Restore Myelin, Safe in Phase 1 Trial

PIPE-307, a new myelin-restoring medication being developed by Pipeline Therapeutics, for treating MS appears to be safe and well tolerated in healthy adults.

The results are from a Phase 1 clinical trial (NCT04725175) that evaluated the safety and tolerability of PIPE-307 in 70 healthy volunteers, ages 18 to 55, at a centre in Australia. It also looked at the medication's pharmacokinetics, or how the medication moves through the body, which was found to be consistent with what was seen in preclinical models. Pipeline therapeutics is a US biopharma specialising in neurodegenerative conditions

"These encouraging Phase 1 results give us great confidence to advance PIPE-307 into clinical studies with MS patients as soon as possible," Stephen Huhn, MD, said in a press release. Huhn is chief medical officer and senior vice president of clinical development with Pipeline. The company expects to move into clinical testing in MS patients after the U.S. Food and Drug Administration gives the green light to an investigational new drug application for the drug.

PIPE-307 blocks the activity of the "M1 muscarinic receptor". This means that it helps oligodendrocyte precursor cells transition into oligodendrocytes. Oligodendrocytes are the myelinating cells of the central nervous system (the brain and spinal cord) that make myelin, a fatty substance that forms a sheath around nerves to protect them and allow these cells to efficiently transmit electrical signals.

PIPE-307 is expected to work by restoring myelin, which becomes damaged in MS. This damage makes it difficult for electrical impulses to be carried to and from the brain along the nerves, causing the symptoms of the disease. PIPE-307 is anticipated to counteract these symptoms.

Currently, there are no approved medicines that work by restoring the myelin sheath around nerves cells so this new drug represents real progress in MS research. **For further information on news stories go to page 14**



Early Years Glandular fever and MS – the missing link for me ?

As someone who suffered severe glandular fever as a seven-year-old and was diagnosed with MS in their late 20s I am naturally interested in the latest research into a link between the two.

My own brush with EBV, or glandular fever as it was called in the 1960s, was quite unpleasant and resulted in me having to take two terms off school and being referred for home teaching by the local education authority.

Although it was 20 years later that I first saw a neurologist, I experienced occasional strange and unexplained health problems in my late teens, around ten years after my childhood glandular fever. These health problems were episodes of double vision which involved trips to an optician who had no idea of its cause

The latest research coming out of Harvard University's TC Chan School of public health is therefore of huge personal interest to me. The research "Longitudinal analysis reveals high prevalence of Epstein-Barr virus associated with multiple sclerosis" was published online in the journal "Science" on January 13, and the press release accompanying it sums up the basic idea that Epstein-Barr virus (EBV) may be the leading cause of MS. It says:

"The hypothesis that EBV causes MS has been investigated for several years, but this is the first study providing compelling evidence of causality. This is a big step because it suggests that most MS cases could be prevented by stopping EBV infection, and that targeting EBV could lead to the discovery of a cure for MS."

To try and firm-up the relationship between EBV and MS, the Harvard researchers led by Alberto Ascherio, professor of epidemiology and nutrition at Harvard's Chan School of Public Health, conducted a study among more than 10 million young adults on active duty in the U.S. military and identified 955 who were diagnosed with MS during their period of service. Ascherio's team analysed serum samples taken every two years by the military. Among the military personnel the risk of MS increased 32-fold after infection with EBV but was unchanged after infection with other viruses. **Continued on page 11**



Continued from page 10 Of course, Ascherio's report shows a clear link between MS and EBV, but for EBV to be accepted as the leading cause of MS there must also be some idea about how EBV causes demyelination, the hallmark of MS. Some of the challenges in making this MS/EBV link are mapped out in a paper entitled "Multiple Sclerosis Is Likely Caused by a Virus", published in the journal "Technology Networks – Immunology and Microbiology". The paper says EBV cannot be the whole story. .

"This raises the question of what other factors are involved. Clearly genetics is often raised as a possible contributor. On a personal level I found this interesting because my late mother (pictured with me above) suffered from ulcerative colitis from her 30s until she died in 2016. An academic paper published in 2007 titled "Association between ulcerative colitis and multiple sclerosis" said "the association between ulcerative colitis and multiple sclerosis appears real." This reality was highlighted in another paper published last year which said "While the estimated prevalence of MS in the general population is 0.1%, the prevalence of the disease jumps to 0.5% in patients with IBD, (Inflammatory bowel disease) suggesting a 1.5 to 5-fold increase in the risk of developing MS in patients with IBD." Inflammatory bowel disease (IBD) is a term mainly used to describe ulcerative colitis and Crohn's disease but interestingly the 2007 paper said: "no association was found between MS and Crohn's disease". I have often reflected on the similarities between MS and ulcerative colitis. Both are relapsing remitting conditions often diagnosed around the age of 30, as was the case for both myself and my mother. Although I never mentioned the MS-UC link to my mother I often reflected that her ulcerative colitis actually placed me at greater risk of getting MS.

Of course, the question that people with MS would like answered is: "will any of this US research lead to a cure for MS?" Already there is an EBV vaccine in development and a US biopharma Atara Biotherapeutics is developing an experimental drug ATA 188 which consists of T-cells that selectively identify and destroy EBV-infected cells. This could reduce the antibodies that those EBV-infected cells produce against the myelin sheath. Ultimately, it could slow or halt disease progression.. Bring it on, I say . **For details of all news and features go to page 13**

Spinal Cord Atrophy Predicts 'Silent Progression' in MS

Spinal cord atrophy, as detected on brain MRI scans, significantly correlates with silent progression of relapsing remitting MS to progressive MS, new research shows.

The research suggests that this is a potentially important biomarker for disease progression that may otherwise go unrecognized by clinicians and patients, investigators note.

"We found that cervical cord atrophy at the C1 level, as obtained from routine brain MRI, is the strongest indicator of silent progression and secondary progressive MS conversion," said lead author Antje Bischof, MD, Department of Neurology and Institute of Translational Neurology, University Hospital, Munster, Germany.

"Silent progression and secondary progressive MS conversion are each predominantly related to spinal cord atrophy," she added.

Bischof presented the findings here at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2022.

Secondary progressive MS (SPMS) generally occurs when relapsing-remitting MS (RRMS) progresses, with relapses ceasing and a more steady accumulation of disability occurring.

However, a relapse-free "silent progression" of MS, described in previous research as occurring in as many as a third or more of patients with relapsing MS, emerges at a much earlier stage prior to secondary progression. This potentially involves widespread neurodegeneration in early disease stages.

"Because the concept of silent progression is relatively new and directly challenges the long accepted two-stage hypothesis, many clinicians have yet to actively identify silent progression in clinical practice," co-investigator Bruce A. C. Cree, MD, PhD, professor of clinical neurology at the University of California, San Francisco (UCSF), told Medscape Medical News.

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News

Trial of remyelinating Drugs Combo Enrols First Patient

The first patient has been enrolled in a new clinical trial testing whether an antihistamine in combination with a diabetes drug might promote the repair of the myelin sheath in MS. Repairing lost myelin — remyelination — is seen by many as a "holy grail" quest for MS treatment.

A Phase 2 clinical trial (NCT05131828), sponsored by the Cambridge University Hospitals NHS Foundation Trust, aims to enrol about 50 adults, ages 25 to 50. Participants will be assigned randomly to take a combination of metformin (500 mg) and clemastine (1.34 mg), or a placebo, by mouth once daily.

Metformin is a medication that is used to control blood sugar in people with diabetes. Research done in preclinical models has suggested that it may improve cognition and promote remyelination, but metformin has never been studied formally in MS.Clemastine is an antihistamine that has been used to control allergies, and research has indicated that it can activate oligodendrocyte progenitor cells, a type of brain cell producing myelin.

A previous study, the Phase 2 ReBUILD trial (NCT02040298), tested clemastine in addition to DMTs in 50 MS patients with chronic damage to the optic nerve, which transmits signals from the eyes to the brain)Results suggested that clemastine treatment improved the speed of signals along the optic nerves, and that this effect persisted for at least two months after stopping the therapy. Since a functional myelin sheath is crucial for neurons to efficiently and speedily send electrical signals, the results indicated that the therapy promoted remyelination.Animal studies suggest that metformin may enhance the effects of clemastine, but the combination has never before been tested in humans.

The new study is currently enrolling participants with a delayed response to stimulus in at least one eye, but without a history of optic neuritis (inflammation of the optic nerve) in the past two years. Enrolment is ongoing at Addenbrooke's Hospital in Cambridge, U.K.

The trial's main goal is to compare the effect of the double treatment against a placebo on the speed of signals along the affected optic nerve after 26 weeks (about half a year). Changes in vision, retinal thickness, and MRI-based measures of myelin damage and repair also will be assessed. **For details of all news stories see page 14**

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