

My prog-MS ezine

For people with progressive MS and other interested people

Issue 59, March/ April 2025

Hello and welcome to the 59th 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 66. (EDSS 6)

In another slightly early Issue, number 59 (I think I am working too hard) there are eight pages of prog-MS news stories about new trials and research and two features. One on page 5 looks at 'brain shrink' in MS. Sadly, in MS your brain shrinks far more quickly than in those without the condition. What are the implications and is there anything you can and should do? See page 5 for my suggestions

There's another feature on page 10 looking at the subject of "MS and work'. It's a sad fact that people with MS leave the workplace in droves after diagnosis. And the rush to the exit continues as the illness progresses. But need it be like this, given that there have been anti-discrimination laws for 30 years, and a plethora of government work schemes? Is it us MSers who are at fault, or does the blame lie with the government or employers?

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News

Tolebrutinib for SPMS gets FDA 'breakthrough therapy' designation

The U.S. Food and Drug Administration (FDA) has granted 'breakthrough therapy designation' to bio-pharma Sanofi's BTK inhibitor drug tolebrutinib to treat adults with non-relapsing secondary progressive MS (nrSPMS).

According to the drug's developer Sanofi, tolebrutinib is the first investigational BTK (Bruton's tyrosine kinase) Inhibitor with the ability to reach the brain which has received the FDA's 'breakthrough therapy' designation. This designation is designed to accelerate the development and regulatory review of medicines intended to treat serious or life-threatening conditions.

'Breakthrough therapy' status will allow Sanofi to have more frequent meetings with the FDA to discuss tolebrutinib's development programme, and also makes the treatment eligible for rolling and priority review. Sanofi is now finalizing an application seeking the approval of tolebrutinib in the US for nrSPMS, and is preparing a similar one in Europe.

The breakthrough designation and planned applications are all based on data from the Phase 3 HERCULES clinical trial (NCT04411641), which tested tolebrutinib against a placebo in more than 1,100 adults with non-relapsing SPMS. The participants had not experienced a relapse in the prior two years but had recent disability progression. The results showed that, after 48 weeks of treatment, tolebrutinib significantly delayed disability progression by 31%, while also doubling the rates of disability improvement compared with a placebo (10% vs. 5%). Participants given the experimental therapy also had a 38% reduction in new or enlarging brain lesions.

The class of therapies to which tolebrutinib belongs is known as BTK inhibitors. These target a protein called Bruton's tyrosine kinase that's essential for the survival and activation of rogue immune cells involved in MS. This breakthrough therapy designation demonstrates the potential for tolebrutinib to delay disability progression, a critical unmet need for people with MS. Tolebrutinib is taken once daily in tablet form.

In addition to the HERCULES trial, Sanofi's clinical development program for tolebrutinib included three other Phase 3 trials: the identical GEMINI 1 (NCT04410978) and GEMINI 2 (NCT04410991) studies, which involve people with relapsing MS, and PERSEUS (NCT04458051), testing tolebrutinib in individuals with primary progressive MS.

PERSEUS is the only trial of the four that's still ongoing. Top-line data for PERSEUS are anticipated for the second half of 2025

For details of sources for all news stories go to page 14

MS-disability worsens after menopause, study finds

MS- related disability starts to worsen significantly faster after menopause, and this worsening may be independent of ageing. That's according to a new study.

The study, "Association of Menopause With Functional Outcomes and Disease Biomarkers in Women With Multiple Sclerosis," was published in the journal 'Neurology'.

Riley Bove, MD, study co-author at the University of California, San Francisco (UCSF), said in a press release. "The study shows that menopause represents a unique factor in MS progression, even when we take into consideration the effects of ageing." Hormone therapy after menopause may help slow MS progression, but more research is needed to test this idea, she added.

MS predominantly affects women and there's evidence that changes in sex-related hormones such as oestrogen may play a role in the disease's progression. During menopause, oestrogen levels drop, so there's reason to think menopause may affect MS disease progression.

"We know that hormonal changes during puberty can trigger autoimmune diseases like MS," Bove said. "We see a lower rate of relapse during the third trimester of pregnancy, followed by a rebound postpartum." (after birth)

Measuring the effects of menopause on MS progression has been difficult, however, and studies attempting to do this have generally relied on the Expanded Disability Status Scale (EDSS) to measure disease progression. The scale has some noteworthy drawbacks as it mainly focuses on walking ability, it isn't very good at capturing subtle changes in people who have some walking difficulties, and scores can be affected by normal ageing that isn't related to MS itself.

"The EDSS has a number of limitations and may also measure changes that are not related to MS, such as older age and multiple medication use, both of which can affect mobility," said Hannah Silverman, first author of the study and a medical student at UCSF.

Nevertheless, the findings lend credence to the idea that the drop in oestrogen during menopause may accelerate the progression of MS. If that's true, then oestrogen-replacing hormone therapies may help stave off disease progression. However, other hormones also change during menopause, so further studies will be needed, the researchers said.

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More evidence that foralumab can lead to improvement in SPMS

A new drug foralumab, delivered as a nasal spray, can control a number of immune cell types in people with nonactive secondary progressive MS (naSPMS), a study has shown. The study also revealed new immune biomarkers that show how foralumab leads to an improvement in naSPMS.

After three months of treatment, gene activity data showed that immune cells including naive B-cells, inflammatory T-cells, regulatory T-cells, and monocytes were affected by foralumab, developer Tiziana Life Sciences said.

Tiziana scientists noted that the immune changes were associated with a reduction in microglial brain inflammation, or a reduction in the activity of brain resident immune cells called microglia, which has been observed in these same patients in PET brain scans. The findings shed additional light on the immune mechanisms through which the therapy exerts its effects in people with nonactive SPMS.

Foralumab works by targeting the CD3 protein at the surface of immune T-cells, which reduces the activity of harmful inflammatory T-cells while increasing the activity of beneficial anti-inflammatory T-cells, known as regulatory T-cells, or Tregs. The drug's anti-inflammatory effect is expected to reduce MS inflammation, which could slow disease progression in people with nonactive SPMS.

Foralumab was first tested in people with nonactive SPMS as part of an expanded access programme. Data from the first 10 patients, all of whom had received treatment for more than six months, showed that 80% had a reduction in microglial activity in PET scans — an indication that brain inflammation was reduced — and 70% had less fatigue after six months. None of the patients experienced a worsening in disability levels over that period, which led the U.S. Food and Drug Administration (FDA) to allow 20 more patients into the expanded access programme.

Foralumab is also being assessed in a Phase 2a clinical trial (NCT06292923) that's enrolling 54 people with nonactive SPMS who experienced at least two years of continuous disease progression despite treatment with available therapies.

Last year, the FDA granted foralumab fast track designation, a status that aims to accelerate the development and regulatory review of experimental medicines that have the potential to fill unmet needs of patients with serious disorders.

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The incredible shrinking MS brain

I hate to admit this, but as someone who has had prog-MS for 20 years 'my brain is shrinking far faster than someone without the condition, and it's something I don't deal with very well.

'Brain shrink' is damage to the brain caused by MS. It tends to primarily affect the myelin-rich white matter but the grey matter is affected too.

A consequence of white matter (myelin) damage spilling over into the grey matter is that your whole brain volume (WBV) shrinks at a rate of up to 1.35% per year, that's nearly three times more than WBV shrinkage in normal ageing which is about 0.5% per year.

This means as someone with MS I am ageing mentally up to three times faster than someone without the condition. I may be in my mid-sixties but having had MS for 30 years I could have the brain of an 80 or 90 year-old man. And to make matters even worse, fatigue is also common in MS, probably as a result of having a smaller brain.

Perhaps the biggest problem of 'brain shrink in my everyday life is something colloquially known as 'cog fog'. In case you are unfamiliar with the term, "cog fog" means that new or demanding tasks become far more tiring and difficult to do. "Cog fog" is one of the problems I find most difficult to accept as my MS progresses. As someone whose MS is now secondary progressive, and someone having 'cog fog' I tend to avoid difficult tasks or do them badly and then have to do them again and again until I get them right.

To give a few personal examples, I seem to spend endless time looking for misplaced items like my front door or car keys when I leave them in new places, or I walk into a room and forget why I am there. Finding the right word or remembering names becomes a huge problem. When it comes to asking me to multi-task you might as well forget it, I usually do.

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Why exactly is this? To give a quick biology lesson here, the brain consists of areas of white matter and grey matter, and both play a vital role in overall mental activity. Grey matter, the outermost layer of the brain, helps with the processing required for daily functioning. It's the thinking part of your brain. White matter serves as a link between grey matter and the rest of the body. It sends messages and tells the rest of the body what is going on in the grey matter.

White matter is found in the deeper part of the brain. It contains nerve fibres surrounded by a myelin sheath which is white in colour, hence the term "white matter". Myelin protects the nerves in the brain and spinal cord, and speeds up the messaging from your brain to other body parts. In MS the immune system attacks the white matter or myelin, causing it to deteriorate and die.

So, faced with these rather depressing facts, one is bound to ask: "Is there anything I can do about it?" I have read that completing crosswords, Sudoku and jigsaw puzzles, even playing chess can help keep your brain fresh and engaged. I have also heard that paying attention to what you eat may help.

The final thing I have been told to consider as a way of fighting cog fog is exercise. As MS advances, exercise becomes more difficult to do. In spite of this, there is every reason to exercise, at least according to a paper published in 2022 in the journal "Multiple Sclerosis and Related Disorders". This paper showed that physical activity as measured as steps per day, correlates with better cognition in MSers.

So, in simple terms, some daily physical activity combined with eating a healthy diet and some challenging mental activity may help me fight cog fog. Improving my diet and cooking skills would be a good place to start. Any recipe suggestions would be most welcome as I would be the first to admit that, despite my surname, I am not a great cook.

Pic p1 & 5 By Jensflorian - Own work, CC BY-SA 4.0, https://commons.wikimedia.org/w/index.php?curid=39237155

For further details of sources for feature see page 14

Large scale trial planned to treat EBV in MS with four drug combo

A large international collaboration of MS experts has recommended using four licensed drugs (famciclovir, tenofovir alafenamide, maribavir and spironolactone) to target Epstein-Barr virus for a Phase 3 clinical trial into EBV (Epstein Barr virus) and its involvement in MS.

Many prog-MSers will be familiar with some of these named drugs. Famciclovir is used to treat the symptoms of herpes zoster (shingles), a herpes virus infection of the skin. It is also used to treat and suppress cold sores (herpes simplex) and recurrent episodes of genital herpes infection. It has been tried in clinical trials for MS where it has been shown to help with neuropathic pain, a common problem in trigeminal neuralgia.

Tenofovir alafenamide is an antiviral medication used against hepatitis B and HIV. It is used for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease and is given in combination with other medications in a drug known as PrEP for the prevention and treatment of HIV. A paper published in 2020 looked at it as a treatment option for MS. Maribavir is an anti-viral drug. Spironolactone, which is primarily a diuretic, also affects the activation of T-lymphocytes and is thought to affect progression of MS mediated by T-lymphocytes (T-cells).

The use of four drugs is unusual in MS where most treatments are mono-therapies '(single drugs). Combination therapy, where several drugs are used in combination, is more typical of HIV treatments where different classes of drugs target the virus in different ways.

The use of combination therapy may be aimed at targeting the Epstein Barr Virus (EBV) at different ways as EBV like HIV never leaves the body, living on in a dormant stage after initial infection and 'cycling' between dormancy and an active or 'lytic' stage during the patient's entire life.

A paper proposing that the four drug trial takes place is titled "Repurposing Licensed Drugs with Activity Against Epstein–Barr Virus for Treatment of Multiple Sclerosis: A Systematic Approach" and was published on January 10, 2025.

Among the listed authors was Gavin Giovannoni, professor at London University well known for his interest in EBV and MS. Other authors included Natalia Drosu of the Department of Neurology, Massachusetts General Hospital and Harvard Medical School, Boston, who has collated research on the link between HERVs (Human Endogenous Retroviruses) and MS.

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News

New EBV vaccine given to first participant in Phase 1 trial

A Phase 1 clinical trial investigating a new vaccine against the Epstein-Barr virus (EBV), a well-established risk factor for developing MS, has dosed its first participant.

The vaccine, called MDX2201, is being developed by Modex Therapeutics, an Opko Health company, in collaboration with Merck (known as MSD outside the U.S. and Canada). The study (NCT06655324) seeks to enrol 200 participants, ages 18-30, at several sites in the U.S. to determine the safety and tolerability of its vaccine, administered via three injections into the muscle over six months. The vaccine's ability to generate an immune response against EBV will also be assessed over about 1.5 years. As a phase 1 safety trial the participants are 'healthy controls' ie: people without MS

Under the collaboration, Modex and Merck have worked together to gain clearance for clinical trials of MDX2201, and Merck is now responsible for leading this and future trials. It will also be in charge of all regulatory activities and for marketing MDX2201, if it is approved in the future. Modex will receive an undisclosed payment for the start of the current trial, and is also eligible for other milestone payments and royalties on global sales.

In MS, EBV is a strong risk factor for developing the condition, increasing its likelihood by about 32 times. It's been shown that some EBV proteins are very similar in structure to certain proteins in the brain, so when the body mounts an immune response to fight the virus, it may inadvertently cause damage to healthy parts of the nervous system.

MDX2201 is a nanoparticle that carries at its surface pieces of several EBV proteins (gp350, gH, gL, and gp42) that mediate EBV's entry into human cells. It is designed to help the body recognize these proteins as harmful, so that an efficient immune response is mounted if the body ever comes into contact with EBV. By targeting four different viral proteins, the approach is expected to be more effective than previous vaccines focusing on gp350 alone.

While vaccines don't treat disease, it is theoretically possible that injecting an MSer with an EBV vaccine might generate a tolerance to EBV, which, if EBV really is involved in MS, might stop the body fighting an EBV infection which happened years or decades earlier. This approach is most highly developed in cancer treatment. Personalised mRNA cancer vaccines are a form of immunotherapy treatment, which are currently being tested in clinical trials. They are tailored to each person's cancer and work by training the immune system to recognise, destroy and prevent the spread of cancer cells. It is theoretically possible that an MS vaccine could lead to an MS treatment immunotherapy. **For details of all news stories go to page 14**

Re-myelination therapy may halt progression

The U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) has allowed a bio-pharma called Pheno Therapeutics to start a 'first-in-human' Phase 1 clinical trial to test its 'oral candidate' (pill or tablet) PTD802 to restore damaged and lost myelin.

The therapy is a selective small molecule antagonist, or inhibitor, of the GPR17 receptor and is designed to restore the damaged and lost myelin — a process known as remyelination — in people with MS.

Current treatments focus mainly on the immune aspects of the disease, reducing severity and frequency of relapses. There is an urgent and unmet need for effective therapies that limit disability progression in MS, with remyelination offering a promising neuroprotective treatment.

The GPR17 receptor works like a natural brake that slows the development of oligodendrocytes, the cells that produce myelin in the brain and spinal cord.

PTD802 is designed to boost remyelination by releasing this brake. Developer Pheno Therapeutics believes it may be used with existing MS therapies to better control disease progression and possibly help patients regain some lost function.

"Whilst GPR17 antagonists have potential utility beyond MS, PTD802 is a hugely promising first-in-class oral remyelination agent, which we believe will be the next step in devising combinatorial approaches to preventing MS progression," said Siddharthan Chandran MD, PhD, Co-Founder of Pheno Therapeutics.

Pheno Therapeutics is based in Edinburgh UK and as we went to press there was no indication of where patients will be recruited for the Phase I trial (They will all be healthy volunteers) but given that Professor Siddharthan Chandran is Dean of Clinical Medicine, Head of Edinburgh Medical School, it seems likely that this first trial will be in Scotland.

For further information go to page 14



Why having MS is bad for your job prospects

In case you weren't aware, figures on employment and MS make grim reading. Statistically, MSers are most likely to leave work a few years after diagnosis, and then things get worse.

As progression creeps in we are likely to spend the rest of our working lives dependent on benefits. Figures on the MS Society website reveal the rate for people with MS who are not working is 59%, while for non-disabled people it is just 19%. Other figures are equally depressing. One study found that 50% of us MSers leave the workplace within ten years of diagnosis and 20 years after diagnosis this figure has shot up to 90%.

What makes these figures most shocking of all is that there has been one government campaign after another during the past 30 years trying to persuade employers and employees to change all this. A few decades ago, there was the government's "two ticks" scheme (logo pictured above) which was all about employers being positive about disabled people. This was replaced by the "Disability Confident" scheme in 2013.

Then there was another government scheme called "Access To Work" which began in 1994. This scheme was set up to provide practical support for disabled people and their employers. There has even been legislation starting with the Disability Discrimination Acts of 1995 and 2005, and culminating in the 2010 Equality Act.

All these measures, while well intentioned, beg the question: why is the unemployment rate for us MSers still so shockingly high, despite all these schemes, initiatives and the like? From a personal perspective the best way to answer this question is to look at my own experience. I am now in my sixties and my working life is drawing to a close. Bucking the trend, I am still employed, and working. So how have I done this? I would be the first to accept I am no 'super hero', and have no special powers, so what is the reason?

Clearly, as a journalist my occupation involves sitting down all day which is a massive help, but good luck or good fortune has also played a huge part in my success. When my diagnosis arrived in 1993, several years after my first symptoms, and I was in my mid-30s, I told my then employer (Central ITV) about it. Central at that time were not only broadcasters of local news but also of a network disability programme called "Link". **Continued on page 11**

Continued from p10 Straight after diagnosis I wandered over to the "Link" office and was warmly met by the programme's blind producer who more or less offered to take me on there and then when I told him about my MS diagnosis. "Welcome to the club," he said.

The next five years I was able to work for this ITV disability programme, and when it was axed I worked for an equivalent BBC2 disability programme called "From the Edge". When this programme too was axed I moved to work on a "Watchdog" spin off programme called "Watchdog Healthcheck" where, being this was the BBC, there was also fairly positive attitude to my MS.

Everything went well MS wise until just after the millennium (ten years after diagnosis) when my MS moved from relapsing remitting to secondary progressive, and my walking and bladder were increasingly affected. The whole daily business of commuting from Surrey to the BBC in Central London each day became impossible. But it wasn't walking or bladder issues that 'did it' for me, it was an eyesight problem called nystagmus.

Work seemed impossible, at least office work and a daily commute was out of the question. It was time for a re-think. Prior to working in TV, I had spent a decade in newspapers. After leaving the BBC in 2002 one of the first things I did was to send in a feature to The Guardian telling the paper I was a self-employed freelance journalist specialising in disability. The feature was about the mis-use of disabled toilets by drug addicts and prostitutes. Incredibly The Guardian published it. https://tinyurl.com/52atr6az Writing commissions from The Guardian and other newspapers came along and 20 years later, and thanks in huge part to New Pathways magazine, published by MS-UK, I am one of the few people who has been able to continue working all the way up to retirement with progressive MS. I am one of the lucky ones.

Luck has played a massive part as has the positive attitude of my employers, family and friends. Yes, I have been lucky but I think there is more than luck. As a teenager I was a constant worrier and my concerned mother bought me a book "How to stop worrying and start living," by the American self-help expert Dale Carnegie.

The book didn't just cover short-term strategies for stopping the "worry bug" it looked at long term strategies for living a worry-free life. Carnegie's top tip was to find a job or career that made you happy. Everyone, he said, can do something. As he put it: "if life gives you a lemon, make lemonade." Looking back, I think MS has been my life's lemon and writing about MS has allowed me to make a lot of lemonade. Fortunately, I absolutely love lemonade, both making it and drinking it. **For details of all features go to page 14.**

News

Immunic 'on track' with clinical trials testing vidofludimus calcium

Bio-pharma Immunic Therapeutics says it remains "on track" in testing its MS treatment candidate vidofludimus calcium in its Phase 2 CALLIPER study involving people with progressive MS. 'Top-line' data from CALLIPER is expected as soon as April this year.

Vidofludimus calcium, also known as IMU-838, is an oral small molecule designed to reduce MS-associated inflammation by blocking a protein called DHODH which is important for immune cell function. Data also suggests the treatment may be able to exert neuroprotective effects by activating a protein called Nurr1. By targeting the disease from multiple angles Immunic believes vidofludimus calcium has promise for treating active progressive forms of MS.

Two identically designed clinical trials called ENSURE, each involving more than 1,000 participants, have been testing the therapy in people with active, secondary progressive MS and relapsing-remitting MS. ENSURE participants receive oral vidofludimus calcium, at a dose of 30 mg, or a placebo, once daily for up to 72 weeks, or nearly 1.5 years. Participants then have the option of entering an open-label extension, in which all will receive vidofludimus calcium for up to eight years. The main goals include measures of brain lesions, brain tissue volume, cognition, and disability.

Another Phase 2 trial called CALLIPER (NCT05054140) is evaluating vidofludimus calcium in 467 adults with secondary progressive MS (SPMS) or primary progressive MS (PPMS) who had no evidence of a relapse in the last two years prior to enrolment.

In this trial, participants have been randomly assigned to receive daily oral vidofludimus calcium or a placebo. The study will span 120 weeks. It also will be followed by an open-label extension period in which all participants will be treated with the investigational therapy for up to eight years. CALLIPER's main goal is to evaluate changes in the rate of brain volume loss, a measure of neurodegeneration. Disability worsening and safety will be evaluated as secondary goals.

Interim data presented last year showed that vidofludimus calcium lowered levels of neurofilament light (Nfl) chain — a biomarker of nerve cell damage — after six months of treatment. That compared with increasing NfL levels over time among those given a placebo. The reductions were seen across MS types, age, and disability levels.
For details of all stories go to page 14

News

PoNS device leads to long-term walking improvement - real-world study says

A 14-week regimen of physical therapy combined with PoNS — a neurostimulator device used to improve mobility — led to significant gait (walking) improvements in MSers, with evidence that its benefits are sustained over time, according to new data from a study called PoNSTEP.

PoNS is a neurostimulator device intended to improve walking and balance in people with MS. It works by delivering light electrical pulses to the tongue, which are transmitted to the brain via two cranial nerves.

This stimulation is believed to promote neuroplasticity, or the brain's ability to rewire in response to new experiences. When used along with physical therapy, PoNS is believed to help strengthen neuronal circuits related to specific tasks, thereby enhancing the benefits of rehabilitation. It's approved in the U.S. for patients aged 22 and older, to be used short term in combination with supervised physical rehabilitation programs. Accumulating evidence has demonstrated the device's ability to improve walking abilities for MS patients

Helius Medical Technologies launched the PoNSTEP study (NCT05437276) to investigate how treatment adherence would influence gait (walking) improvements for patients using its PoNS device in a 'real-world setting'.

The study enrolled 41 Msers with walking difficulties who started a 14-week regimen of PoNS along with physical rehabilitation. This included two weeks of in-clinic treatment supervised by a physical therapist, followed by 12 weeks of unsupervised at-home therapy. Participants were then followed for six months in a post-treatment observation period.

The study's main goal was to evaluate changes in dynamic gait index (DGI), which assesses a person's ability to maintain balance during various physical tasks.

Results indicated a statistically significant improvement in dynamic gait index (DGI) at week 14 among the 38 participants who completed the treatment protocol, according to developers Helius. Specifically, the average DGI improved by 5 points over the treatment period.

For details of all news stories see page 14

References further details, etc

Page 2 Tolebrutinib

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Page 3 Menopause role in worsening MS disability

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Pages 5-6 The incredible shrinking MS brain

For studies on the positive effects of exercise on the MS brain see a 2016 study https://pubmed.ncbi.nlm.nih.gov/27219279/ and a 2019 study https://pubmed.ncbi.nlm.nih.gov/31096850/

Page 7 Trial of four drug combo planned to treat EBV in MS

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Page 10-11 Work and MS

For some examples of my journalistic work on disability for both The Guardian and ITV see below

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Page 13 PoNS device shows some positive results in clinical trials

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To see the PoNS device being used go to https://heliusmedical.com/about-pons/

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