

My prog-MS ezine

For people with progressive MS and other interested people

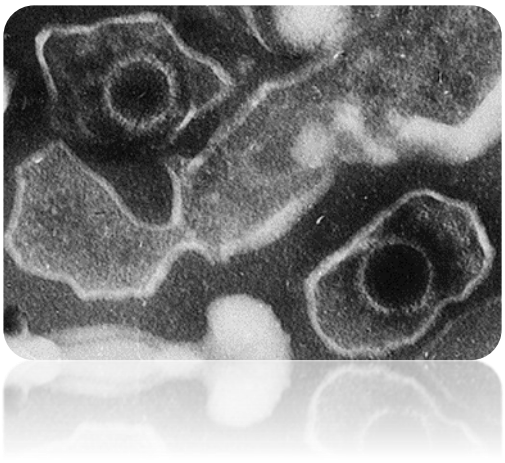
Issue 52, January/ February 2024

Hello and welcome to the 52st 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 65.

In this 52nd issue, there are as usual eight pages of prog-MS news stories. There are also two features. One on page 5 looks at ATARA BIO's long awaited trial results for its treatment into a therapy which aimed to tackle EBV (Epstein Barr virus) in MS. The feature asks: why did the trial fail?

There's another feature on page 10 looking at some amazing Italian research which tested a three-drug combo for MS, and reported disability (EDSS) scores dropping by a remarkable average of 4.02 points after just 45 days treatment! Too good to be true? You be the judge.
Picture below : EBV virions Author Liz Gross
http://biology.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pbio.0030430 Sourced from Wikipedia

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Shock as EBV drug ATA188 is worse than placebo in prog-MS trial

In a major surprise, the experimental cell therapy ATA188 which targets the Epstein-Barr virus in MS, failed to outperform a placebo at easing disability in people with nonactive progressive forms of the condition.

That's according to data from the Phase 2 portion of the EMBOLD clinical trial. ATA188 also showed no signs of efficacy on certain MS disease biomarkers.

As no benefit from treatment was observed, Atara Biotherapeutics will likely be stopping the EMBOLD study and substantially cutting back on expenses related to ATA188. The company said it plans to refocus its resources on treatments in other diseases.

Epstein-Barr virus (EBV) has been identified as a major risk factor for MS. Most people have been infected with EBV by the time they reach adulthood. After an infection, the EBV virus lives in an inactive state inside immune B-cells. ATA188 is a cell-based therapy containing another type of immune cell, T-cells, derived from healthy people who have been infected with EBV.

The therapy specifically contains T-cells that are primed to kill EBV-infected B-cells, with the hope that destroying the infected cells might slow the progression of MS. The EMBOLD Phase 1/2 clinical trial (NCT03283826) tested ATA188 in people with nonactive progressive forms of MS, including secondary progressive MS (SPMS) and primary progressive MS (PPMS).

In the Phase 1 portion of the study results had been promising, with roughly a third of patients showing notable improvement in disability, defined as a meaningful reduction in Expanded Disability Status Scale scores that is confirmed in a follow-up visit. In the Phase 2 part of the trial only 6% of patients on ATA188 showed disability improvement, as compared to 16% of those given a placebo.

Scientists at Atara now will analyse this data in-depth, in an attempt to understand why the proportion of patients given ATA188 who experienced disability improvement was so much lower in the Phase 2 part of the study compared with the Phase 1 portion. Researchers also hope to determine why so many people given a placebo experienced disability improvement, as only about 4%-6% of patients would be expected to have improved without treatment due to natural variations in disease severity over time.

"We are further evaluating the EMBOLD data as we continue to believe in the critical role EBV plays in MS [disease development], however we anticipate stopping the study as no treatment benefit was observed," an ATARA spokesperson said.

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Trial of HIV drug PrEP in 50 MS patients to report in December 2024

A phase II clinical trial is due to report at the end of 2024 testing whether the anti-viral HIV drug PrEP works in MS. The trial further explores the hypothesis that a virus, probably EBV or Epstein Barr virus, is the driver of the disease.

The research study is taking place in the US and aims to find out if the existing HIV drug also known as Truvada (tenofovir/emtricitabine), used mainly as a drug to stop HIV positive people passing on the virus to HIV negative people, is also active against the Epstein Barr virus (EBV). The trial will test EBV levels in saliva and blood in people with MS given Truvada.

The trial is built on the well-known theory that MS is, in part, triggered by infection with the Epstein Barr virus (EBV), and that targeting the virus with an anti-viral drug could be a more effective and safer strategy for MS treatment than immunomodulation or immunosuppression alone.

The evidence supporting a causal role for EBV in MS has come from numerous studies over the past 20 years that have shown similarities in the distribution of EBV infection and MS, a 2-3 fold increased MS risk among individuals with a clinical history of infectious mononucleosis (glandular fever), and also compelling evidence that MS rarely, if ever, develops in individuals who are not infected with EBV.

More recently, a study based on the US Department of Defence Serum Repository with samples from over 7 million young adults free of MS who were EBV-seronegative at the start of the study showed they did not develop symptoms of MS until at least several months after infection with EBV. High serum antibody levels of the EBV-encoded nuclear antigen-1(a sign of infection) were associated with an over 30-fold increase in MS risk.

Antiviral agents repurposed from treating other herpes viruses, like acyclovir or valacyclovir, have had virtually no effect against EBV in studies of glandular fever and MS. However certain preparations of the HIV drug tenofovir, such as tenofovir disoproxil fumarate (TDF), are significant and potent inhibitors of EBV replication in cell culture more so than other anti-viral drugs that have been found to be clinically ineffective for EBV.

TDF is a safe drug used clinically for HIV pre-exposure prevention (PrEP) in HIV-negative patients and is sold as the drug Truvada. Truvada has been widely used since its approval in 2004 for the treatment of HIV and has a well-known safety profile that makes it a good candidate for clinical studies so there should be no safety issues with the trial which started in June 2023 and has enrolled 50 participants who will take TDF for three months. It is due to report its results by the end of December 2024. The trial has been supported by the US patients' organisation Solving MS https://solvingms.org/

For details of all news stories go to page 14

Is the common bacteria C. perfringens a trigger for MS progression?

Researchers from Rockerfeller University in the US have discovered a potential link between the bacteria C. perfringens (Clostridium perfringens) and MS progression.

The research suggests that a toxin from the bacteria might be responsible for breaking down the blood-brain barrier, a key event in MS and its progression. It also sheds light on a potential environmental trigger for MS and paves the way for possible treatments hinting at the prospect of developing a vaccine in the near future.

Interestingly C. perfringens is prevalent in regions with high sheep populations, and people living in these regions have a high incidence of MS. Also, research shows 61% of MS patients had high levels of epsilon-toxin-producing C. perfringens in their guts compared to 13% of healthy individuals. C. perfringens is a common microbe found in sewage, marine sediment, soil, and the Gastro-intestinal (GI) tracts of pets and farm animals

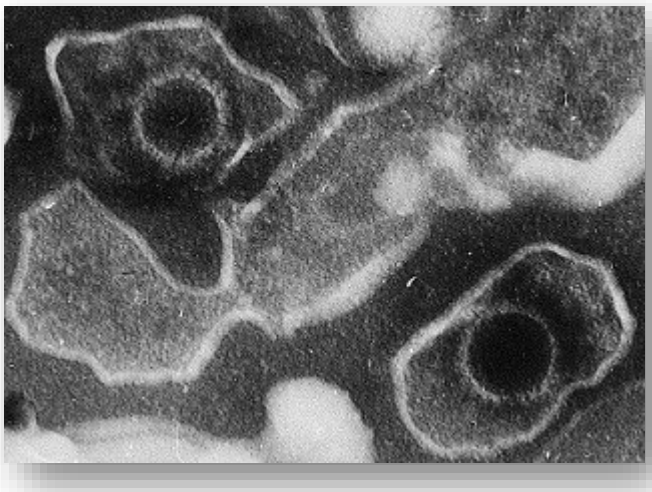
The findings of the research, published in The Journal of Clinical Investigation, suggests that a toxin produced by certain C. perfringens bacteria may be the long sought-after trigger that degrades the blood-brain barrier and kicks off the relentless inflammation and brain cell degradation characteristic of MS.

“If this is the environmental trigger for MS, we can now start talking about a vaccine, monoclonal antibodies, or some other therapy,” says Rashid Rumah, co-author of the study and a physician scientist in Vincent Fischetti‘s lab at Rockefeller University.

Scientists have long suspected MS is precipitated by an environmental trigger; likely some sort of microbial infection. The question was which microbe was to blame. While searching for an answer, Rumah stumbled across a 1986 study that highlighted an unexpected correlation: people living in areas with high sheep populations, such as Scotland and New Zealand, are more likely to suffer from MS. Rumah thought of one potential culprit.

“The bacteria C. perfringens, often found in sheep, makes over 20 different toxins, Its epsilon toxin has been known to break down the blood-brain barrier and cause MS-like symptoms in sheep.” In the hopes of further exploring epsilon toxin as a possible environmental trigger for MS, Rumah joined Fischetti’s lab in 2008. After several years, the team amassed evidence that epsilon-toxin-producing C. perfringens are to blame. The team’s immediate goal is to find definitive evidence linking epsilon toxin to MS. “We need to move from the gut and show that epsilon toxin is in the serum and cerebrospinal fluid of MS patients in the active phase of the disease,” Rumah says. “If we can detect the toxin in the blood, then we’d have irrefutable evidence that this is at play in MS**.”**

For further details see page 14.



So, why did the ATA1888 trial into EBV in MS fail?

You will doubtless know by now that Atara Bio's phase 2 EMBOLD trial of ATA188 in non-active progressive MS failed. If it's any consolation, Atara says it's reviewing its figures, including the 6% disability improvement in the group taking ATA188 compared to a 16% disability improvement those taking the placebo or dummy drug.

I rubbed my eyes in disbelief when I read the above figures. I asked myself why was there such a big improvement in those taking dummy pills compared to those taking the real drug. I emailed Atara asking if they are going to investigate the possibility they mixed up the results. I have not heard anything so far.

Assuming that the Atara figures ARE correct, we have to ask: did the trial failed because it was trying to prove the wrong hypothesis - EBV (Epstein Barr virus or glandular fever) causes MS? Or is the hypothesis correct but the trial testing it poorly designed?

I dismiss the "incorrect hypothesis" idea because the evidence supporting EBV as the cause of MS is so compelling. But before moving on I would like to add a caveat. The overwhelming evidence that EBV is the cause of MS tells us loads about EBV infection pre-dating MS but little about how MS develops years after an EBV infection in a very small number of cases – far less than 1%. We desperately need to know more about the process of how EBV can reappear years later as MS in a tiny minority. **Continued on page 6**

Continued from page 5 There are two views about this. The first view is that EBV primes the body to get MS years later and then goes away (the hit-and-run hypothesis). The second is that EBV drives the disease via its "latent-lytic cycling" (the "disease driver" hypothesis). Given that EBV like other herpes viruses such as cold sores (herpes simplex) have a tendency to return and then "drive" the disease via this "latent -lytic cycling" process (flare-ups followed by virus dormancy) I tend to go with this idea. Iit's known EBV lies dormant in B-cells and it is the infected B-cells that then carry EBV into the Central Nervous System through the blood brain barrier - the so-called 'Trojan Horse' hypothesis The ATA188 Embold study tested this hypothesis, but there have been arguments about how the trial was set up. ATA188 was a treatment based on allogeneic (donor cells) not autologous cells ie: cells taken from the MSers taking part in the trial then treated and re-infused. For this reason, the donor cells, it is argued, were not perfect matches.

Another point is that EBV like other herpes viruses develop clever techniques for switching off T-cells coming to help the cells EBV infects. This is how herpes viruses persist. It is critical to know whether ATA188 re-infused allogenic T-cells maintained their active EBV killing mode when re-infused. Perhaps they didn't. Atara Bio will doubtless say correctly that allogeneic (donor) EBV-specific T-cells work in patients with EBV-associated cancers, therefore, it's argued, should work against EBV in MS. However, I ask if this assumption is correct.

So, what will these results mean for the EBV hypothesis of MS? Hopefully, the ATA 188 debacle will have no impact on MS/EBV research. And it is re-assuring to see that a trial of PrEP, a HIV drug combining emtricitabine and tenofovir disoproxil fumarate which is thought to have an impact on EBV, as well as HIV, is now taking place in the US. Clearly, the failure of the ATA 188 trial has not ended interest in the idea that EBV is the cause of MS. What is doubly impressive is that this US trial is taking place thanks to the involvement of an MS patients' group called Solving MS https://solvingms.org/ which goes to show that patient-power will probably lead to us closer to finding a cure to MS. The trial, which is taking place at Massachusetts General Hospital started in June 2023 and is due to report in June 2024 so it's certainly worth looking out for.

One final point worth considering is the amazing placebo-response rate in the confirmed disability improvement of 16% in the EMBOLD study. If this is correct it tells us that despite progressive MS, a large number of us CAN recover function. If ATA 188 was achieving an improvement in earlier prog-MS trials by a placebo effect alone, it is a sobering example of how highly motivated we progressive MSers are to get better.

Picture p5: EBV virions Author Liz Gross http://biology.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pbio.0030430 Sourced from Wikipedia

For further details see page 14

Four new SPMS patients dosed with nasal foralumab outside of trials

Tiziana Life Sciences has dosed four new participants in an expanded access programme investigating its foralumab nasal spray in people with nonactive secondary progressive MS, the company has announced.

A total of 10 SPMS patients are now being followed outside of clinical trials in foralumab's expanded access programs (EAPs), which are taking place at the Brigham and Women's Hospital (BWH), in Boston USA.

EAPs allow individuals with serious or life-threatening conditions to have access to an experimental treatment outside of patient trials when there are no alternative therapies available. To date, two patients have received foralumab as part of single-patient access programmes, and the remaining eight are being treated in an intermediate-size EAP, according to a company press release.

Tiziana will use the data from the EAPs to obtain information on dosing and patient feedback, which will support the design of future studies. The company recently launched a Phase 2a clinical trial to investigate foralumab in people with nonactive SPMS. It was expecting to enrol the first participant before the end of 2023.

Foralumab is a human antibody-based therapy designed to reduce brain and spinal cord inflammation associated with MS and other neurodegenerative diseases. It works by blocking the CD3 receptor at the surface of immune T-cells, inhibiting these cells' activity and reducing inflammation, while boosting the activity of regulatory T-cells that prevent excessive immune reactions. According to the company, nasal delivery — using a nose spray — can potentially improve the treatment's safety, tolerability, and efficacy compared with intravenous or into-the-vein infusions.

A Phase 1 clinical trial demonstrated that the therapy was safe and well tolerated in healthy volunteers. Moreover, it was able to modulate the immune system toward an anti-inflammatory response.

So far, the two patients in the single-patient access program have received the medication for more than one year, and the first four on the intermediate-size program have been dosed for at least six months. None has had serious side effects. Data from positron emission tomography (PET) scans demonstrated that five of these six patients had reductions in the activity of microglia — brain resident immune cells known to contribute to MS progression — at three and six months. In addition, two patients experienced a reduction in disability, meaning that some of their symptoms eased after starting on the therapy. In the remaining four, disability scores remained stable over at least six months of treatment.. **For details of all news stories go to page 14**

MS linked to another common herpes virus – this one's called HHV6a

Researchers at Sweden's Karolinska Institute have found people with MS are highly likely to test positive for another herpes virus in addition to the Epstein Barr virus (EBV) also known as Human Herpes Virus 4 (HHV4). The Swedish research points to a role for a second herpes virus HHV-6A in the development of MS.

Herpes virus 6A is common in young children but has not until now been associated with any disease. However, the new Swedish research, published in Frontiers in Immunology, shows people with MS had a 55 percent higher risk of carrying antibodies against HHV-6A than a control group. The new work suggests that two herpes infections could be acting jointly to increase the risk of MS.

According to estimates, as many as 80 percent of all children are infected with the HHV-6A virus before two years of age, and many also carry protection in the form of antibodies against it for the rest of their lives. But it hasn't until now been possible to tell if HHV-6A is a risk factor for MS.

"This is a big breakthrough for both the MS and herpes virus research," says Anna Fogdell-Hahn, associate professor at the Department of Clinical Neuroscience at Karolinska Institute and one of the study's senior authors. It supports the theory that HHV-6A could be a contributing factor to the development of MS."

In the Karolinska Institute study, researchers compared antibody levels in blood samples of some 8,700 MS patients with more than 7,200 healthy individuals. They noticed that people with MS had a 55 percent higher risk of carrying antibodies against the HHV-6A protein than the control group.

In a subgroup of almost 500 people whose blood samples were drawn before the onset of the disease, the risk of developing MS in the future was more than doubled if they had a HHV 6A viral infection. The younger the people were when the virus was first discovered in the blood, the higher the risk was of developing MS in the future.

Antibodies toward EBV (HHV4) were analysed with the same method, and the researchers were able to show that individuals affected with both viruses had an even greater risk of MS. This indicates that two herpes virus infections could be acting jointly to increase the risk of MS.

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EBV vaccine prevents infection in lab-grown human cells

EBV-001, a vaccine candidate being developed by bio-pharma EBViously to target the Epstein-Barr virus (EBV), triggered the production of potent antibodies against the virus in mice, and blood samples from these animals preventing EBV infection in lab-grown human cells.

That's according to new data presented by the company, which is developing the vaccine as a way to prevent EBV infections. EBV infections are implicated in infectious mononucleosis, known commonly as glandular fever, MS and at least four cancers.

The new preclinical data was presented at the World Vaccine Congress West Coast 2023, held Nov. 27-30 in Santa Clara, California. The presentation was given by Sebastian Goy, PhD, designated chief operating officer at EBViously.

The company, which is a spinoff from Helmholtz Munich, part of a German government research network, says it expects to start clinical trials in 2024 to test its EBV vaccine candidate in humans. The first trial will aim to prevent mononucleosis due to EBV infection, which also has been linked to a higher risk of MS.

"In addition to a strong preclinical data package, we now have everything in place for the start of clinical trials," Axel Polack, MD, EBViously's designated CEO, said in a company press release. "Following further confirmation of our preclinical efficacy data, we will apply for regulatory clearance to proceed towards a Phase I study."

EBV-001 is an experimental vaccine that mimics the original virus, carrying in its shell more than 50 viral proteins that can be recognized by the immune system to launch an attack when in contact with the actual virus. However, it does not contain any viral genetic material, so it cannot cause an infection.

EBViously reported previously that the vaccine generated an immune response in animal models, which included cellular immunity and the production of antibodies against the virus. These reactions reflect the broad spectrum of antiviral immunity in humans.

The new data presented by the company demonstrates that even at low levels, EBV-001 induces a specific and strong B-cell response in mice, leading to the production of high levels of antibodies against several viral proteins. Researchers also collected sera — the fluid component of the blood that contains antibodies — from these animals. It was able to prevent EBV infection of human B-cells and skin cells in lab cultures.

For further information go to page 14



Would combination therapies work in MS?

For me, one of the curiosities of MS disease modifying treatments is that they all seem to be single drug therapies, something known as monotherapies.

I find this puzzling given the complexity of the illness. Even if, you accept that Epstein Barr virus (EBV) is the main driver of the disease, as I do, then there is still a lot more to explain and treat. An anti-EBV drug might stop a virus causing problems for us MSers, but there is clearly a lot more going on in MS than just a nasty viral infection going into over-drive.

To give a few examples of the yet to be unanswered questions surrounding MS: what explains why MS is more common in women than men? Why is it more common in certain parts of the world? And why does MS seem to have a genetic component?

The idea that a single drug, a sort of silver bullet, will work on the genetic, geographical and gender components of the disease as well as EBV is, I think, overly optimistic and I wonder if another approach might be more effective. If you look at HIV and cancer the idea of combining two or three different therapies which all target the condition in different ways is now widely accepted.

I was therefore heartened to hear recently of a study called “Project Amythest” being carried out in Italy which has tried out three drugs, an antibiotic, a statin and an anti-fungal to treat neurodegeneration in MS. The three drugs when taken together have led, it is claimed, to some amazing improvements in 60 people with MS over a period as short as just one month.

Project Amythest is the brainchild of 51 year old Italian lawyer Fabrizio Di Silvestri who was diagnosed with MS in his twenties, shortly after the millennium. Following his diagnosis he made it his life’s work to find an effective treatment for the condition. He studied forensic and naturopathic medicine. Armed with this new knowledge and some fresh thinking about how to treat MS he carried out a study with the help of sympathetic medical staff, MS patients and controls, and is now hoping to organise a clinical trial for his new combination therapy or multi-drug treatment. **Continued on page 11**

Continued from p10 A preliminary study in Italy enrolled 90 MS patients, aged 25 to 65, and 60 healthy adults as a control group. The aim was to show his new treatment's potential to prevent neurodegeneration in MS. Participants were given two doses of three drugs daily for 45 days, along with a controlled diet.

The drug combination was 100 mg minocycline (an antibiotic), 20 mg atorvastatin (a statin), and 50 mg fluconazole (an anti-fungal) in a single dosage taken once every 12 hours.

The idea of combining an antibiotic, a statin and an anti-fungal as an MS treatment is interesting because all three types of drug are either already being used, being tested or have already been tested as MS treatments. Minocycline has been researched as a possible MS treatment. One paper was published as recently as 2019. The immunomodulating properties of minocycline have been found to impact neurological diseases in animal experiments. Other studies have revealed the drug's anti-inflammatory and neuroprotective effects.

Statins are currently being tried out in a clinical trial called MS-STAT2 where high dose (80 mg) daily doses of Simvastatin are taken by people with secondary progressive MS to see if the drug can slow progression. Results are due later this year. Finally, when it comes to anti-fungals many people may be unaware that the commonly prescribed di-methyl fumarate MS disease modifying drug (Tecfidera) is actually an anti-fungal. The MS Society website puts it: "We don't know exactly how it works" That said, one can't rule out the fact that its anti-fungal properties may be playing a part.

Results of Fabrizio Di Silvestri's "three drug combo" have indicated significant reductions in disability, reflected by lower Expanded Disability Status Scale (EDSS) scores. Specifically, patients' average EDSS score dropped by a remarkable average of 4.02 points after just 45 days of treatment. Improvements in motor control and balance, better bladder control, as well as reductions in fatigue, also were reported. MRI scans indicated that the therapy led to reductions in brain lesions.

The investigations are now moving to a new higher level with the involvement of some bio-pharmaceutical companies and plans for bigger clinical trials. Frankly, the results of the preliminary study are quite amazing.

The optimistic in me reading the above figures makes me think that Project Amethyst could possibly be the silver bullet or three silver bullets we have all been waiting so long for. As a realist I have to add that only time will tell. Hopefully we will hear more about Project Amethyst in 2024.Photo (p10) by Louis Reed on Unsplash **For details of all news and features go to page 14**

News

Ibudilast plus beta-interferon to get European patent for prog-MS

Bio-pharma MediciNova has announced the approval of a European patent covering the use of ibudilast in combination with beta-interferon-medications to treat both primary and secondary progressive MS.

The patent will apply to a wide range of doses, and dosing frequency and duration for both medications. It will also cover the use of the two therapies simultaneously or consecutively, and administered in the same or in separate dose forms. Patent protections would be valid at least until October 2039.

A similar U.S. patent covering this combination therapy and its use in treating progressive MS forms was granted previously.

Ibudilast is an oral small molecule designed to lower the levels of pro-inflammatory signalling molecules that contribute to MS-driving inflammation and nerve cell damage.

A Phase 2b clinical trial, called SPRINT-MS (NCT01982942), analysed the effects of ibudilast in 255 people with PPMS or SMPS, with or without relapses.

Participants were randomly assigned to either ibudilast or a placebo for 96 weeks (almost two years), and those being treated with glatiramer acetate or interferon-beta MS therapies could continue their use. Interferon-beta therapies, contain a naturally occurring signalling molecule that immune cells use to reduce excessive inflammatory responses and better protect nerve cells.

SPRINT-MS demonstrated that ibudilast significantly slowed by 48% brain volume loss compared with a placebo, with a much stronger effect in PPMS patients. Its use also helped to protect nerve cells of the retina, a light sensitive layer of the eye whose thinning is associated with brain degeneration.

Moreover, “analysis of the data from our completed Phase 2b trial in progressive MS indicated that there may be a synergistic effect of the combination of [ibudilast] and interferon-beta which could result in an even lower risk of disability progression compared to the risk reduction for [ibudilast] alone,” a spokesperson for MediciNova said.

For details of all stories go to page 14

€4.6 million New Funding to speed New Treatments for Progressive MS

The International Progressive MS Alliance is funding two major initiatives to help find new, effective treatments for people with progressive MS.

The first initiative called “Challenges in Progressive MS Awards” will advance promising initial findings from six projects that received exploratory grants in 2021 to improve understanding of mechanisms that drive progression.

The second initiative “Innovations in Well-Being Awards” are the first phase of a large-scale programme of research to identify and implement solutions to some of the most challenging symptoms of prog-MS. Nine projects have been awarded funding to develop expert teams with the potential to develop, test and implement new therapies.

Overall, these seventeen pilot projects have already received exploratory funding. The International Progressive MS Alliance is now announcing the funding of the six larger and longer-term “Challenges in Progressive MS Awards” from the above 17 projects

These “Challenges in Progressive MS Awards” will focus on several areas including novel insights into axonal loss in progressive MS, molecular pathways that promote neuroprotection and repair, and the testing of potential drugs to slow progression.

The Challenges in Progressive MS Awards are three-year research projects with work initiating in early 2024 and reporting findings in 2027.

As well as The Challenges in Progressive MS Awards, the Alliance is also funding nine Innovation in Well-Being Awards. These awards are the first stage of a well-being research pipeline in which successful awards will demonstrate a strong expert team and research proposal that offers the potential for novel therapeutic interventions or outcomes for progressive MS and can culminate with a large randomized controlled study (Stage 2) and implementation (Stage 3) for adoption into healthcare systems around the world.

The nine projects will focus on the symptoms of pain, mobility, impaired cognition and fatigue. The first phase of the research projects will initiate in early 2024 and report results in mid-2025

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References further details, etc

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Page 3 PrEP trial taking place in US to report in December

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page4 C. Perfringens and MS

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Page 8 Another herpes virus -HHV6a - implicated in MS

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Page 9 EBV vaccine prevents infection in lab grown human cells

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