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[www.neurozone.org](http://www.neurozone.org)

We have seen significant growth in the last year at 21<sup>st</sup> Century Neurology. Founded in April of 2001, the clinic focuses on conditions affecting the body's nervous system: the brain, spinal cord, muscles and nerves. These include Multiple Sclerosis, Alzheimer's disease, Parkinson's disease, epilepsy, peripheral neuropathy, migraine, and atypical pain syndromes like postherpetic neuralgia, fibromyalgia, and trigeminal neuralgias. We are recruiting for clinical trials aimed at providing new therapeutic approaches to these diverse conditions. If you or someone you know is interested in a clinical trial, please call us or see our website for updated information.

Fibromyalgia has been a perplexing disease. It has taken nearly twenty years to make progress in its diagnosis, but effective treatments have been lacking. A new approach to fibromyalgia is recognizing that it is really a disorder of sleep. During sleep, muscles rest and regenerate, but if sleep is disrupted by poor breathing (sleep apnea), restless movements, or fragmentation with frequent awakenings the muscles never get a chance to regenerate, leading to the muscle aches and tender points seen in fibromyalgia. This view leads to an interesting idea being tested now in a clinical trial sponsored by Jazz Pharmaceuticals (Palo Alto, California), the makers of Xyrem (sodium oxybate), a drug approved for treating narcolepsy. Xyrem is an enhancer of slow wave sleep, and in a phase II trial showed benefit in reducing daytime pain in patients with fibromyalgia. We are now recruiting for a phase III trial of Xyrem; if successful, the drug may win approval as the first drug indicated for fibromyalgia.

Multiple sclerosis is a demyelinating disease of the central nervous system. A number of exciting new approaches to therapy have recently emerged. Opexa Pharmaceuticals (The Woodlands, Texas) is conducting a Phase II trial in relapsing-remitting multiple sclerosis of a novel T-cell vaccine which is made from a patient's own blood. This is a first for 'personalized medicine' and may be a route to a landmark definitive treatment for MS.

A desirable goal for MS has been oral therapy. Novartis Pharmaceuticals (Basel, Switzerland) has been testing fingolimod (FTY720), an oral agent which sequesters immune cells in the lymph nodes. As a follow-up to a successful phase II study, an international phase III trial is under way. Teva Pharmaceuticals (Jerusalem, Israel) is launching a large phase III trial of their oral agent, laquinimod. In phase II it showed a 44% decrease in active lesions on MRI. Other oral agents previously studied have included steroids, Cytosan, Imuran, Cyclosporine and Cellcept. The future looks bright for oral treatment of MS.

Other immune system modulators are racking up successes in clinical trials for MS. Intravenous Rituxan (Genentech; South San Francisco, California), a drug approved for treating non-Hodgkin's lymphoma and rheumatoid arthritis, has had

good phase II results. While other monoclonal antibody treatments similar to Tysabri (Biogen Idec; Cambridge, Massachusetts) are in late clinical trials, Tysabri itself is being used in nearly 10,000 patients worldwide and has been well-tolerated.

XEN Institute, our sister non-profit organization, is gearing up its new Institutional Review Board to review new clinical trials. The IRB is part of the federal oversight system which regulates development of drugs, tests and medical devices. It is hoped that once the IRB is self-sufficient its profits can directly fund XEN Institute sponsored research. Two very exciting areas for XEN include genomics, for which a large grant was received from Teva Pharmaceuticals, and development of cell replacement therapies. Support is needed for XEN's mission to fund advanced research in neurology. As XEN is a 501(c)(3) organization, all donations are tax-deductible. See [www.xeninstitute.org](http://www.xeninstitute.org) or call (602) 265-6500.

Device treatments may be the future of neurology. Our neurologists now offer both DBS (deep brain stimulator) and VNS (vagus nerve stimulator) for advanced treatment of a variety of conditions. DBS can completely suppress tremor, manifestations of Parkinson's disease, and dystonia, and is now being looked at for epilepsy, depression, and Tourette syndrome. VNS is approved as an adjunct for treating partial seizures and treatment-refractory depression, although the Centers for Medicare Studies has controversially denied coverage of VNS for depression, an odd situation which most observers feel will be resolved in favor of coverage eventually. Both devices require a pulse generator which is implanted in the chest like a regular pacemaker; DBS also requires two electrodes placed in the thalamus or basal ganglia deep within the brain. In our office, patients come to have the generator programmed to optimally treat their condition. While no therapy is universally advantageous, most patients' conditions improve with VNS or DBS implantation, often dramatically. They also offer the potential to reduce medication, sometimes cutting doses in half, or reducing multiple drug regimens to a single drug in addition to the electrical therapy.

Therapy with RNA is heating up with the promise of individualized treatment for genetic disorders like Huntington's disease. Two companies, Sirna (now part of Merck; Whitehouse Station, New Jersey) and Alnylam Pharmaceuticals (Cambridge, Massachusetts), are working to make RNA therapies a reality. It may be possible to make a traditional style 'one fits all' drug for each genetic disorder, but researchers are now realizing that since each patient's genes are different it may be necessary to create a unique treatment just for him or her. We can predict this could lead to a radical shift towards personalized medicine, which could change the way the pharmaceutical industry and medicine in general operate. \*