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NEWS RELEASE

THE QUEBEC NEUROLOGISTS' ASSOCIATION CALLS FOR CALM Treatment of Multiple Sclerosis by Venous Angioplasty

Montreal, March 22, 2010 – In recent weeks, a number of news media have been interested in a new approach called the “liberation treatment” for patients with multiple sclerosis. This treatment developed by Dr. Paolo Zamboni and his team in Ferrara, Italy, is based on a new theory that hypothesizes that the cause of multiple sclerosis is occlusions of veins which drain blood from the brain and the spinal cord, two areas affected by multiple sclerosis.

In a scientific article published in December 2009, Dr. Zamboni reported his results after treating 65 patients with multiple sclerosis: 35 patients with the relapsing-remitting type and 30 patients with a progressive type of the disease. In this study, treatment consisted of venous angioplasty, or the insertion into the veins of a catheter with the objective of removing venous obstruction by expanding a balloon at the site of occlusion. According to this study, patients suffering from the relapsing-remitting type observed a slight decrease in the frequency of their attacks in the 18 months following their surgery. They also noted an improvement in the multiple sclerosis composite score that is used to measure the time it takes to walk a distance of 25 feet, hand coordination and concentration on a cognitive task. For patients with the progressive disease, the study showed no improvement in mobility and in the questionnaire, only a slight improvement on the quality of life was rated at six months, but absent 18 months after treatment. The vast majority of these patients were treated with immunomodulatory therapy, which is recognized as effective in the treatment of multiple sclerosis. No major complication has occurred in these patients, but 50% of them presented a new vein stenosis.

The presentation of this study by W5 on CTV last November, before any article was published in a scientific journal, has raised great hope among patients with multiple sclerosis. Given the distress that the disease causes for people who suffer from it, many patients now want to benefit from the treatment proposed by Dr. Zamboni.

However, it is important to understand that the final conclusions of the scientific article by Dr. Zamboni acknowledge that this is only a pilot study and may be biased by the absence of control cases for comparison and by the fact that this study was not done blind, that is to say that the neurologist knew that patients had been treated, thus providing a possible bias. Dr. Zamboni recommended starting more comprehensive research protocols to verify his conclusions.

In fact, a control study is currently under way at the Jacobs Neurological Institute in Buffalo and the Multiple Sclerosis Society of Canada and the National MS Society of the United States will fund various groups' research by June 2010. As the results are only preliminary, this study cannot eliminate all doubt that the beneficial effects observed are the result of coincidence associated with the natural evolution of multiple sclerosis. This treatment will not be available in Canada until it is part of a research protocol duly recognized by an ethics committee. A physician offering the treatment in Canada outside a research protocol and for compensation would violate the code of ethics of the medical profession and be subject to reprimands from his professional association.

Many people with MS still want to benefit now from this treatment. Medical centres in India, Poland and Bulgaria are offering MS patients angioplasty venous for payment ranging from \$8,000 to \$20,000. However, these treatments will not be followed up or be the subject of a research protocol. In recent weeks, patients took advantage of a platform provided by television networks TVA and LCN to express their intention to go abroad for treatment. These news stories are encouraging a number of people with the disease to also consider going abroad to receive treatment.

Whereas the results of Dr. Zamboni's study are only preliminary, and his study is based on a hypothetical cause of the disease that has not yet been confirmed, the results are only mild and limited to patients with relapsing-remitting MS. In his findings, Dr. Zamboni acknowledges that it is only a pilot study and requires confirmation by further randomized studies. Given the fact that the treatments currently available overseas are not made within a research protocol, the Association of Neurologists in Quebec (ANQ) does not recommend that Quebec patients travel abroad for treatment by venous angioplasty. In the same way as the network of multiple sclerosis clinics in Canada where neurologists treat patients with the disease in Canada, the ANQ recommends people not to stop their usual treatment. Contrary to the impression that is conveyed by the media, the results published by Dr. Zamboni do not suggest that angioplasty is a cure for the disease. Patients treated continue to suffer from active multiple sclerosis. The ANQ believes that because of the risks involved in this type of treatment and since the benefits appear to be limited, for the time being, it is preferable for patients with the disease to wait for the results of further research.

Multiple sclerosis is the most widespread neurological disease causing disability in young adults. An estimated 10,000 to 12,000 people suffer from MS in Quebec. It usually strikes people between age 20 and 40 and affects more women than men by a ratio of 2 to 1. The majority of patients (80%) first have a relapsing-remitting form of the disease, that is to say, episodes or attacks with various neurological symptoms (visual loss, paralysis, numbness, dizziness) subsiding in a few days with partial or complete recovery of symptoms in subsequent weeks. These patients will have other attacks in subsequent years. They can live normally without limitation in the early stage of the disease. In some people the disease will evolve over the years into a progressive form. With the advanced type, patients no longer have attacks, but note a gradual loss of neurological function without recovery. Patients with the progressive type are generally more severely affected by the disease.

The cause of the disease is unknown, but a number of studies suggest it is partly caused by genetic predisposition and unknown environmental factors. It is related to inflammation affecting the brain and spinal cord (central nervous system). This inflammatory reaction is autoimmune, that is to say that there is abnormal production of antibodies attacking the patient's own organs. Since 1996, a number of new drugs have been available to treat the disease and help reduce the severity of inflammatory attacks on the central nervous system to decrease the frequency and severity of relapses and delay the onset of the progressive form of the disease. Although imperfect, these drugs have improved the quality of life of patients suffering from multiple sclerosis and many new treatments will be available in the coming years.

For more information:
J. Marc Girard, M.D., President
Association des neurologues du Québec
514-350-5122