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Prot.

To whom it may concern

Cluster headache (CH) in an excruciating form of primary headache characterized by recurrent unilateral, attacks of very severe pain that last up to 3 hours and are accompanied by oculo-facial autonomic symptoms and signs and restlessness. Typically the attacks recur several times/24 hours in active periods (the so-called clusters) separated by pain-free remission periods.

Due to the excruciating severity of pain the disability in this illness is very severe, and suicidal risk exists in this patient population. In a recent US survey, 55% of the CH population has had suicidal thoughts, while 2% have actually tried to commit suicide (Rozen and Fishman, 2011). Recent data have documented that the burden related to CH is significant. Indeed patients with active CH are more severely impaired than migraineurs in economic and non-economic domains, such as working life, disability and psychiatric complaints (Jurgens et al. 2011).

Symptomatic care for CH relies on evidence-based treatments such as sumatriptan s.c. and high-flow oxygen, which may provide rapid and effective relief in most patients if taken at the onset of the attacks. Unfortunately these treatments often have serious disadvantages. Sumatriptan cannot be prescribed to patients with cardiovascular comorbidity, its use is limited by adverse effects and it is not safe if assumed more than two times a day. Furthermore its regular use for more than 10 days in a month may cause medication-overuse headache, especially in those patients with migraine comorbidity.

High-flow oxygen is safe and effective, but oxygen tanks are unwieldy and inconvenient and as documented by a recent survey (Rozen and Fishman 2010) it is underprescribed and difficult to obtain. Indeed in many EU countries its use is not officially recognized by the healthcare systems and patients have to pay for it.

A limited number of prophylactic medications are available for CH, but they are associated with a variable rate of effectiveness, a high rate of side-effects and, in some cases, with a potentially severe toxicity (i.e. lithium carbonate)

CH deserves attention and care because it is intrinsically a seriously disabling disease, and even more so because the currently available treatments do not meet the needs of many CH sufferers. In this view, the availability of a new therapeutic option such as civamide definitely fulfils an unmet medical need in providing an additional therapeutic alternative for this excruciating pain.

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Il Responsabile del procedimento: tel.:

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Sistema Sanitario  Regione Lombardia