MEDIA RELEASE

14 September 2011

Australian Chronic Migraine Sufferers Set To Benefit from BOTOX®

- BOTOX® provides relief for disabling condition that often goes undiagnosed and untreated[1,2] -

BOTOX® (botulinum toxin, type A) is now available Australia-wide as an effective treatment option for adults living with Chronic Migraine,[2,3] a debilitating condition that affects over 345,800 Australians.[3,4]

Chronic Migraine is defined as patients experiencing headaches for 15 days or more per month with a migraine on at least eight of these days.[5] Migraines – a disabling type of headache - can last four hours or longer each day.[5]

BOTOX® is the latest therapy available in Australia for the prevention of headache in adults suffering from this complex neurological disorder.[2,3]

According to Associate Professor Richard Stark, Neurologist, Chronic Migraine stops sufferers in their tracks, often preventing them from even basic activities.

"Chronic Migraine is a distinct and devastating condition. Due to the severity and frequency of the headaches, people with Chronic Migraine find it hard to function in their daily lives. Their migraines can last for days. Tasks such as working or caring for children can prove challenging and sometimes are not even possible," he said.

As reported in the World Health Organisation (WHO) Bulletin, a day lived with severe migraine, either 'episodic' (occasional) or 'chronic' (frequent) is as disabling or more so as a day lived with dementia, active psychosis, paraplegia, blindness or rheumatoid arthritis.[6] As the most severe

type of migraine, Chronic Migraine is associated with substantial physical, social, psychological and economic burden for its sufferers, yet it often goes undiagnosed and untreated.[1,5]

“Chronic Migraine is not widely recognised and often goes undiagnosed. Furthermore, the condition is made more complex as people with Chronic Migraine tend to overuse strong painkillers to deal with the frequent headaches. This acute medication use can cause more headaches and perpetuate the problem, so having access to a specific treatment that is effective in preventing Chronic Migraine symptoms is a significant step forward,” commented Professor Stark.

BOTOX® is a new addition to the treatment options available for Australians diagnosed with Chronic Migraine,[2] following the world’s largest clinical trial to date on this condition.[3]

Specifically for Chronic Migraine sufferers, the results show that treatment with BOTOX® can significantly reduce the number of headache days per month, in addition to reducing acute medication use and increasing the number of migraine-free days (compared to pre-treatment).[3,7]

Also reducing the severity of headaches, BOTOX® treatment can improve a Chronic Migraine patient’s quality of life (compared to pre-treatment).[3]

To determine the impact of migraine on sufferers, Headache Australia and Allergan recently surveyed 435 people who are affected by the condition. The results highlighted that migraine has a notable negative impact on the lives of people who suffer from them, be it occasionally or regularly.

Almost half (47 per cent) of all respondents stated that their migraines had a notable negative impact on their quality of life (rating 8 or above on a Richter Scale with 10 being ‘significantly negative’).[8] Approximately three out of five (61 per cent) describe the pain of a migraine as ‘unbearable and agonising’.[8]

Over a third (36 per cent) of regular migraine sufferers (9 or more migraines per month) reported that they were prevented from going to work on more than two occasions per month due to the condition, and 42 per cent said they were prevented from working full time.[8]

Furthermore, more than three out of four (87 per cent) of regular migraine sufferers reported that the condition had a significant impact on their personal relationships.[8]

“Migraines, whether episodic or chronic, can disable a person and drastically reduce their quality of life and those around them. The recent survey results further highlight this. It is important that people suffering migraines see their GP and ensure that they are diagnosed correctly, as there are new treatments that might be more effective and appropriate for their condition,” said Gerald Edmunds, Secretary General of Headache Australia.

Since the inclusion of BOTOX® for Chronic Migraine on the Australian Register of Therapeutic Goods (ARTG), Allergan has been focused on training key neurologists and certain pain specialists across Australia to be able to effectively treat those patients that are eligible.

For regular headache and migraine sufferers to understand how the condition is impacting them, Professor Stark recommends keeping a diary: “A diary allows people to record how frequently they suffer from headaches. If they look to be suffering from them on more than 15 days per month, they should think about speaking with their GP about being referred to a neurologist in order to discuss their condition and treatment options.”

Administered by a trained neurologist or pain specialist, BOTOX® can be used for the prophylaxis (prevention) of headaches in Chronic Migraine patients aged 18 years or over and can provide relief for up to three months.[2]

-ENDS-

PBS Information: BOTOX® is not listed on the PBS for Chronic Migraine

For a full copy of the BOTOX® Consumer Medicine Information, please see attached document.

Information about BOTOX® (botulinum toxin type A) treatment

BOTOX® (botulinum toxin type A) purified neurotoxin complex is a prescription medicine containing 100 units (U) of botulinum toxin type A for injection.

Therapeutic class: neuromuscular blocking agent.

**Indications: ***Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine); strabismus; blepharospasm associated with dystonia, including benign blepharospasm & VIIth nerve disorders (hemifacial spasm) in patients 12 years & over; cervical dystonia (spasmodic torticollis); focal spasticity of the upper & lower limbs, including dynamic equinus foot deformity due to spasticity in juvenile cerebral palsy patients 2 years & older; severe primary hyperhidrosis of the axillae; focal spasticity in adults; spasmodic dysphonia; upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults.

Contraindications: Hypersensitivity to ingredients; myasthenia gravis or Eaton Lambert Syndrome; infection at injection site(s).

Precautions: Different botulinum preparations are not therapeutically equivalent. Exercise extreme caution should substitution with another botulinum preparation be necessary. Botulinum toxin effects may be observed beyond site of local injection with symptoms consistent with mechanism of action and reported hours to weeks after injection. Symptoms may include muscular weakness, ptosis, diplopia, blurred vision, facial weakness, swallowing and speech disorders, constipation, aspiration pneumonia, difficulty breathing and respiratory depression. Risk of symptoms is greatest in children with spasticity, but can also occur in adults particularly those on high doses. Swallowing/ breathing difficulties can be life threatening and there have been reports of death (relationship to BOTOX® not established). Use with aminoglycosides or drugs that interfere with neuromuscular transmission; peripheral motor neuropathic diseases or neuromuscular junctional disorders; *hypersensitivity reactions such as anaphylaxis and serum sickness, as well as urticaria, soft tissue oedema and dyspnoea; inflammation at injection sites; excessive weakness in target muscle; pregnancy & lactation. Generalised weakness & myalgia may be related to systemic absorption. Blepharospasm: Reduced blinking following injection of the orbicularis muscle can lead to corneal pathology. Caution with patients at risk of angle closure glaucoma, including anatomically narrow angles. Strabismus: Inducing paralysis in extraocular muscles may produce spatial disorientation, double vision or past pointing. Use in chronic paralytic strabismus only in conjunction with surgical repair to reduce antagonist contracture. Spasticity: Not likely to be effective at a joint affected by a known fixed contracture. Cervical Dystonia (spasmodic torticollis): Possibility of dysphagia or dyspnoea. May be decreased by limiting dose injected into the sternocleidomastoid muscle to <100U. Primary Hyperhidrosis of the Axillae: Consider causes of secondary hyperhidrosis to avoid symptomatic treatment. Spasmodic Dysphonia: Laryngoscopy in diagnostic evaluation is mandatory. Avoid treatment in patients due to have elective surgery requiring general anaesthesia. *Chronic migraine: Due to difficulties in establishing a diagnosis of chronic migraine, patients being considered for prophylaxis of headaches with BOTOX® should be evaluated by a neurologist or

pain management specialist prior to receiving treatment with BOTOX®. Paediatric Use: Safety & effectiveness below 18 years have not been established for chronic migraine and below 12 years not established for blepharospasm, hemifacial spasm, cervical dystonia, hyperhidrosis, spasmodic dysphonia or upper facial rhytides. Safety & effectiveness below 2 years not established for focal spasticity. Caution should be exercised when treating patients with significant disability & co-morbidities and elderly. Caution should be exercised after treatment of BOTOX® as it can have an effect on the ability to drive and use machines.

Interactions with other Medicines: The effect of botulinum toxin may be potentiated by aminoglycoside antibiotics or spectinomycin, or any other drugs that interfere with neuromuscular transmission (e.g. tubocurarine-type muscle relaxants). Caution should be exercised when BOTOX® is used with aminoglycosides (e.g. streptomycin, tobramycin, neomycin, gentamycin, netilmycin, kanamycin, amikacin), spectinomycin, polymyxins, tetracyclines, lincomycin or any other drugs which interfere with neuromuscular transmission. No specific tests have been carried out to establish the possibility of clinical interaction with medicinal products. No drug interactions of clinical significance have been reported.The effect of administering different botulinum neurotoxin serotypes at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Adverse Reactions: Usually transient & occur within first week of injection. ≥1% Localised pain, tenderness, bruising, infection, local & general weakness, erythema, oedema, ptosis, irritation/tearing, vertical deviation, diplopia, sub-conjunctival & conjunctival haemorrhages, reversible increase in intra-ocular pressure, trigger finger, clumsiness, falling, hypokinesia, increased frequency of micturition, joint dislocation, muscle spasms, convulsions, nasopharyngitis, pneumonia, vomiting, contusion, leg pain/cramps, fever, knee pain, ankle pain, lethargy, arm pain, hypertonia, fever/flu syndrome, accidental injury, incoordination, paresthesia, asthenia, headache, hyperkinesia, neck pain, dysphagia, perceived increase in non-axillary sweating, vasodilation, paralytic dysphonia (breathy dysphonia), aspiration, stridor, technical failure, blepharoptosis, face pain, ecchymosis, skin tightness, nausea, temporary lateral lower eyelid droop, eyebrow ptosis, eyelid swelling, aching/itching forehead, feeling of tension, seizures, migraine*, facial paresis*, musculoskeletal stiffness*, myalgia*, musculoskeletal pain*, muscle tightness*, injection site pain*, pruritus*, rash*.

**Please note change(s) in Product Information*

If you would like any further information or to arrange an interview please contact:

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About Allergan

Founded in 1950, Allergan, Inc., with headquarters in Irvine, California, is a multi-specialty health care company that discovers, develops and commercialises innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential — to see more clearly, move more freely, express themselves more fully. The company employs approximately 10,000 people worldwide and operates state-of-the-art R&D facilities and world-class manufacturing plants. In addition to its discovery-to-development research organisation, Allergan has global marketing and sales capabilities with a presence in more than 100 countries.

References:

1. Bigal ME *et al*. Chronic migraine in the population: burden, diagnosis and satisfaction with treatment *Neurology* 2008; 71: 559-566.

2. BOTOX® Approved Product Information.

3. Diener HC *et al*. OnabotulinumtoxinA for treatment of chronic migraine: Results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. *Cephalalgia* 2010;30(7):804-814.

4. Estimate based on extrapolation from global data and calculation of number of adult Australians (aged 18 and over) from Australian Bureau of Statistics 2010, *Australian Population by Age and Sex, Australian States and Territories, June 2010* cat. no. 3201.0, ABS, Canberra, Table 9.

5. Manack A *et al*. The Evolution of Chronic Migraine: Classification and Nomenclature. *Headache.* 2009;49:1206-1213.

6. Harwood RH *et al*. Current and future worldwide prevalence of dependency, its relationship to total population, and dependency ratio. *Bulletin of the World Health Organisation*. 2004;82(4):251-258.

7. Dodick DW *et al.* OnabotulinumtoxinA for Treatment of Chronic Migraine: Pooled results from the double-blind, randomized, placebo-controlled phase of the PREEMPT clinical program. *Headache*. 2010;50(6):921-936.

8. Headache Australia and Allergan Survey. August 2011. **Survey findings also filtered to include responses from those who stated that they suffered from 9 or more migraines per month.*

AU/0248/2011c