

**MEDIA RELEASE**

[Insert embargo time and date] March 2014

**CHRONIC MIGRAINE TACKLED HEAD-ON*****BOTOX® (botulinum toxin type A) receives government subsidy for debilitating condition***

**Sydney, Australia, [insert date]:** More than 450,000 Australians are likely to be living with chronic migraine,<sup>1,2</sup> a debilitating condition where patients experience headache on 15 or more days per month with at least eight of these with migraine symptoms, now have another treatment option to prevent the onset of their migraine headaches.<sup>3,4</sup> From 1 March, BOTOX® (botulinum toxin type A) will be available on the Pharmaceutical Benefits Scheme (PBS), for the preventative treatment of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least eight are with migraine).<sup>4,5</sup>

A migraine is a severe and debilitating condition, whereby sufferers can experience visual disturbances such as flashing lights and blind spots along with nausea and vomiting. Due to the high frequency of the headaches, many people struggle to cope in their daily lives, anxious about when the next attack might occur. People suffering from chronic migraine in particular, are twice as likely to suffer from depression and severe anxiety, due to missed days at work and loss of income.<sup>6</sup>

Currently, it is estimated that over 80 per cent of Australians experiencing chronic migraine have not been diagnosed.<sup>2</sup> According to Dr Con Yiannikas, Neurologist, Royal North Shore Hospital, "Chronic migraine is vastly under-recognised and under-diagnosed. Many people suffering from several attacks a month continue to only take treatment at the onset of a migraine rather than look at how they can prevent migraine. People experiencing 15 headaches a month should ask their GPs to refer them to a neurologist to discuss how best to treat their condition and explore preventative treatment options," concluded Dr Yiannikas.

The World Health Organisation (WHO) Bulletin has highlighted the social and economic burden of chronic migraine on sufferers, comparing a day lived with severe migraine to a day lived with dementia or blindness.<sup>7</sup> Similarly, the public perception of chronic migraines by non-sufferers is that they are not life-threatening and they are not a serious health condition.<sup>8</sup>

"The decision to make this preventative therapy widely available must be congratulated. Chronic migraine is a disabling condition and BOTOX® provides another potential treatment option for patients and their neurologist to consider as they strive for optimal health outcomes." Dr Yiannikas added.

Gerald Edmunds, CEO of Headache Australia, welcomes the addition of BOTOX® treatment for the prevention of chronic migraine to the PBS: “Many people have difficulty understanding the devastating impact chronic migraine can have on a person’s life – a migraine attack can completely disable a person, causing them to have nausea and vomiting, unable to tolerate light and sound, leaving them crippled with pain.”

“The PBS reimbursement of BOTOX® will provide another treatment option for adults suffering from chronic migraine in Australia. Providing access to this specific treatment also highlights the Government’s recognition of chronic migraine as a medical condition that requires neurologist intervention,” added Gerald Edmunds.

### **About BOTOX®**

BOTOX® (botulinum toxin type A) is a natural, purified protein that is used to treat a variety of medical conditions including chronic migraine. The active ingredient in BOTOX® is derived from bacteria in sterile laboratory conditions in much the same way penicillin is manufactured from mould. As it is a prescription-only medicine, BOTOX® treatments are only available from qualified medical professionals.<sup>4,5</sup>

The recommended dose for the preventative treatment of chronic migraine is 155 U to 195 U administered intramuscularly as 0.1 ml (5 U) injections across 7 specific muscle areas in the head and neck. The injections should be repeated every 12 weeks. The patient should not receive more than 3 cycles before an assessment of the need for further treatment.<sup>4</sup>

Common side-effects associated with BOTOX® in the preventative treatment of chronic migraine include neck pain and muscular weakness. (Adverse events chosen are  $\geq 5\%$ ).<sup>4,5,9</sup>

**-Ends-**

**Note to editors:** Dr Con Yiannikas has been involved with clinical trials sponsored by Allergan and has served on Advisory Boards for Allergan and other pharmaceutical companies for which he has received financial compensation. He has not received payment from Allergan in relation to this media announcement.

**PBS Information: Section 100 restriction.  
Refer to PBS schedule for full information.**

**Before prescribing, please review Approved Product Information available on request from Allergan.**

**Australian Minimum Product Information**

**BOTOX® (botulinum toxin type A) purified neurotoxin complex** is a prescription medicine containing 100 units (U) or \*200 units (U) of botulinum toxin type A for injection. **Indications:** \*Overactive bladder with symptoms of urinary incontinence, urgency and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication \*urinary incontinence due to neurogenic detrusor overactivity resulting from a defined neurological illness (such as spinal cord injury or multiple sclerosis) and not controlled adequately by anticholinergic agents; 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:** \*Intradetrusor injection - acute urinary tract infection, acute urinary retention in patients who are not routinely catheterising, or who are not willing and/or able to initiate catheterisation post-treatment, if required; 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). Serious adverse events including fatal outcomes have been reported in patients who had received BOTOX® injected directly into salivary glands, the oro-lingual-pharyngeal region, oesophagus and stomach. 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®. \*Bladder Dysfunction: The intradetrusor administration of BOTOX® is only to be conducted by a urologist/urogynaecologist trained in this technique or by a urologist/urogynaecologist under the direct supervision of a urologist/urogynaecologist who has been so trained. \*Caution when performing cystoscopy. \*Assess post-void residual volume post-treatment. \*Overactive Bladder: Patients treated may show increased likelihood of developing urinary retention and/or urinary infection. Men with overactive bladder and signs or symptoms of urinary obstruction should not be treated with BOTOX®. \*Neurogenic Detrusor Overactivity: autonomic dysreflexia associated with the procedure could occur, which may require prompt medical therapy. Paediatric Use: Safety & effectiveness below 18 years have not been established for urinary incontinence due to \*overactive bladder or neurogenic detrusor overactivity, 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:** The effect of botulinum toxin may be potentiated by aminoglycoside antibiotics or any other medicines that interfere with neuromuscular transmission. Caution should be exercised when BOTOX® is used in patients taking any of these medicines. 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, dyspnoea, pneumonia, dry mouth, vomiting, contusion, leg pain/cramps, fever, knee pain, ankle pain, lethargy, arm pain, hypertonia, fever/flu syndrome, accidental injury, incoordination, paraesthesia, 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, \*urinary tract infection, \*urinary retention, fatigue, insomnia, constipation, muscular weakness, gait disturbance, bladder diverticulum, haematuria, \*dysuria, autonomic dysreflexia, \*bacteriuria, \*residual urine volume, \*pollakiuria. **Dose/Administration:** Use one vial for one patient. Store reconstituted BOTOX® in refrigerator; use within 24 hours of reconstitution. \*Overactive Bladder: 100U injected in the detrusor muscle. Neurogenic Detrusor Overactivity: 200 U injected in detrusor muscle. Chronic migraine: 155U to 195U administered intramuscularly (IM) divided across 7 specific head/neck muscle areas. Blepharospasm: Initially 1.25U to 2.5U injected into upper lid medial & lateral pre-tarsal orbicularis oculi & into lower lid lateral pre-tarsal orbicularis oculi. Cumulative dose over 2 months should not exceed 200U. Strabismus: Initial doses 1.25 – 2.5U to 2.5 – 5.0U per muscle. Maximum single injection for any one muscle is 25U. VIIIth Nerve Disorders (hemifacial spasm): Dosing as for unilateral

blepharospasm. Inject other facial muscles as needed. Focal Spasticity in Children 2 Years & Older: 0.5-2.0U/kg body weight for upper limb & 2.0-4.0U/kg body weight for lower limb. 4U/kg or 200U (the lesser amount) for equinus foot deformity. Other muscles range 3.0-8.0U/kg body weight & do not exceed 300U divided among muscles at any treatment session. Focal Spasticity in Adults: Individualise dosing. Cervical Dystonia (spasmodic torticollis): Individualise dosing. Maximum dose 360U every 2 months. Primary Hyperhidrosis of the Axillae: 50U intradermally to each axilla in 10-15 sites 1-2 cm apart. Spasmodic Dysphonia: Bilateral injections. Individualise dosing. Glabellar Lines: 2x4U in each corrugator muscle & 4U in the procerus muscle for 20U total dose. Crow's Feet: 2-6U/injection site, 3 sites bilaterally in lateral orbicularis oculi. Forehead Lines: 2-6U/injection site, 4 sites in frontalis muscle. Date of TGA approval: 06 August 2013

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

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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.

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**References:**

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<sup>1</sup> Natoli JL et al. Global prevalence of chronic migraine: A systematic review. *Cephalalgia* 2010;30(5):599–609

<sup>2</sup> Bigal ME et al. Chronic migraine in the population: Burden, diagnosis and satisfaction with treatment. *Neurology* 2008;71(8): 559-566

<sup>3</sup> Manack A et al. The Evolution of Chronic Migraine: Classification and Nomenclature. *Headache* 2009;49(8): 1206-1213

<sup>4</sup> BOTOX® Approved Product Information

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<sup>5</sup> BOTOX® Approved Consumer Medicine Information

<sup>6</sup> Buse DC et al. Sociodemographic and comorbidity profiles of chronic migraine and episodic migraine sufferers. *J Neurol Neurosurg Psychiatry* 2010;81(4):428-432

<sup>7</sup> Harwood RH et al. Current and future worldwide prevalence of dependency, its relationship to total population, and dependency ratios. *Bulletin of the World Health Organisation* 2004;82(4):251-258

<sup>8</sup> World Health Organisation. Headache Disorders fact sheet no. 277. October 2012. Accessed 13 December 2013 via <http://www.who.int/mediacentre/factsheets/fs277/en>

<sup>9</sup> Aurora SK et al. OnabotulinumtoxinA for Treatment of Chronic Migraine: Pooled Analyses of the 56-Week PREEMPT Clinical Program. *Headache* 2011;51(9): 1358-1373