

## NTL & NSW CONSUMER MEDIA RELEASE

### **New treatment option for schizophrenia – Reagila® – to be listed on PBS**

- **Adults living with schizophrenia will have access to a new treatment option with Reagila® (cariprazine) reimbursed on the Pharmaceutical Benefits Scheme from 1 September, 2021.<sup>1</sup>**
- **There continues to be a significant, unmet need in treating schizophrenia. With a complex range of symptoms,<sup>2</sup> treatment is not a “one size fits all”.<sup>3</sup> This listing will give adults living with schizophrenia, another affordable, mental illness treatment.**
- **Affecting approximately 90,000 Australians,<sup>4</sup> schizophrenia is considered our nation’s most disabling, and heavily stigmatised mental illness,<sup>5</sup> with the average life expectancy of those with the illness, 12.5 to 16.5 years below that of the general population.<sup>4</sup>**

**EMBARGOED: 7:30AM AEST, SUNDAY, 29 AUGUST, 2021**

**MELBOURNE** – A new treatment for schizophrenia in adults, Reagila® (cariprazine), will be listed on the Pharmaceutical Benefits Scheme (PBS) from 1 September, 2021, providing patients with an additional treatment option.<sup>1</sup>

Schizophrenia is a complex psychiatric disorder<sup>2</sup> comprising a range of symptoms, including positive symptoms, such as hallucinations and delusions,<sup>6,7</sup> and negative symptoms, such as social withdrawal and apathy.<sup>8,9</sup>

Reagila® – in-licensed by Seqirus, a wholly-owned subsidiary of CSL – is an atypical antipsychotic which indirectly targets two neurotransmitters in the brain – dopamine and serotonin.<sup>10</sup> Neurotransmitters are considered the brain’s ‘chemical pathways’.<sup>11</sup>

Approved in the US since 2015, and EU since 2017, Reagila® is now approved in over 52 countries for the treatment of schizophrenia in adult patients.<sup>12</sup>

Co-Director for Health and Policy, Brain & Mind Centre, The University of Sydney, and NHMRC Senior Principal Research Fellow, Professor Ian Hickie, Sydney, said this new listing highlights ongoing efforts to provide new treatments for schizophrenia, and the need to ensure people living with the mental illness, have affordable access to a wider range of treatments.

“The complex nature of schizophrenia,<sup>2</sup> whereby people experience a range of different problems, means treatment is not a “one size fits all”.<sup>3</sup> Additional options are most welcome, and help to reduce the current barriers to effective treatment,” said Prof Hickie.

“The annual cost to Australian society of psychosis is an estimated \$6 billion. However this figure does not account for the impacts endured by individuals, their families, and the supporting community.<sup>4</sup>

“Schizophrenia is a complex and often persistent mental illness. It not only affects brain function and behaviour, but is also associated with serious impacts on physical health. Consequently, it is associated with very high rates of premature death,<sup>13</sup> often due to preventable illnesses, such as heart disease, diabetes, infections, accidents and suicide,”<sup>14,15</sup> Prof Hickie said.

Mental Illness Fellowship of Australia (MIFA) CEO, Tony Stevenson, Brisbane, welcomed the reimbursement of a new treatment option for those living with schizophrenia.

“The availability and accessibility of affordable treatment options for adults living with schizophrenia is crucial for this patient community, given the stigma they experience with the disorder<sup>15</sup>, and resulting social isolation,”<sup>8,9</sup> said Mr Stevenson.

“Sadly, stigma can contribute to the impact of psychosis in schizophrenia, delays in accessing treatment, social isolation, stress, and furthermore, places those affected at higher risk for a more severe course of illness.”<sup>16</sup>

According to mental health advocate and policy advisor living with schizophrenia, Richard, 40, Sydney, “mental illness does not make you ‘crazy’, ‘dangerous’, or less of a person. It can be an inevitable part of life, and we should accept the illness, just as we do with a physical illness.”

“Everyone needs love and hope, and this applies to those living with a mental illness too,” Richard said.

“Timely and affordable access to a range of treatment options plays an important role in effectively managing schizophrenia, while importantly, arming the patient community with hope.

“Love gives you a sense of self-worth – of being appreciated, having a net, and not being lonely. Hope gets you up in the morning, and helps to continue one’s relationship with mental illness,” said Richard.

Seqirus Head of Medical Affairs Asia Pacific, Dr Jonathan Anderson, Melbourne, said the Australian Government’s investment in innovative medicines, like Reagila<sup>®</sup>, was important to ensure Australians have timely and affordable access to treatments which may help to address the unmet need in schizophrenia.

“Seqirus is proud to make Reagila<sup>®</sup> available in Australia for the first time, and we thank the Australian Government for their support in delivering this PBS listing – ensuring Australian adults living with schizophrenia can access this innovative medicine, and do so in an affordable way,” Dr Anderson said.

“We know that additional investment in treatment options and support is critical to changing the statistics for people living with schizophrenia, their carers, family and friends.”

**ENDS**

## **MEDIA CONTACTS**

### **Joanne Cleary**

#### **Seqirus**

Senior Manager, Communications

Mobile: 0428 816 751

Email: [Joanne.Cleary@seqirus.com](mailto:Joanne.Cleary@seqirus.com)

### **Kirsten Bruce**

#### **VIVA! Communications**

Principal

Mobile: 0401 717 566 / 0421 551 257

Email: [kirstenbruce@vivacommunications.com.au](mailto:kirstenbruce@vivacommunications.com.au)

### **Mel Kheradi**

#### **VIVA! Communications**

Senior Account Manager

Mobile: 0421 551 257

Email: [melorin@vivacommunications.com.au](mailto:melorin@vivacommunications.com.au)

## **DIGITAL MEDIA KIT**

[www.schizophreniamediakit.com.au](http://www.schizophreniamediakit.com.au)

## **VNR**

[www.vimeo.com/592544606/d1188a8813](http://www.vimeo.com/592544606/d1188a8813)

## ABOUT SEQIRUS

Seqirus, a CSL company, is a leading provider of essential vaccines and pharmaceuticals. We have served Australia's healthcare needs for over a century, and today we operate Australia's only local manufacturing facility for seasonal and pandemic influenza vaccine. Seqirus produces a range of unique medicines in the National Interest, and also in-licences a broad range of paediatric and adult vaccines and specialty pharmaceutical products. <http://www.seqirus.com/>.

## ABOUT REAGILA®

Reagila® was TGA approved in November 2020 as a Schedule 4 (Prescription Only Medicine).<sup>17</sup> Reagila® is indicated for the treatment of schizophrenia in adult patients. Reagila® will be listed on the PBS from 1 September, 2021 for schizophrenia, and requires a Streamlined Authority prescription.

## SIDE-EFFECTS

The most common side-effects of Reagila are feelings of restlessness, inability to sit still, and Parkinsonism. The common side-effects are weight increase; decreased or increased appetite; abnormal level of lipids; sleep disorders or sleepiness; anxiety; dizziness; involuntary twisting movements and strange postures; excessive teeth grinding or jaw clenching; drooling; persistent blinking; movement problems; tongue movement disturbance; blurred vision; fast, irregular heartbeat; high blood pressure; nausea (feeling sick); vomiting; constipation; increased liver enzymes; increase of an enzyme found in your heart/brain/skeletal muscles. These are mild to moderate side-effects of Reagila®. Other rare or serious side-effects may also occur.<sup>18</sup> Speak to your healthcare professional or doctor for more information.

## FURTHER INFORMATION

Reagila® is not recommended for use during pregnancy, and in women of childbearing potential not using effective contraception. Breastfeeding is not recommended whilst taking Reagila®. For further information, including Contraindications, Precautions, and Interactions, refer to the Product Information and Consumer Medicine Information, or your doctor or pharmacist.

Reagila® Consumer Medicine Information can be found [here](#).

## Disclosure statement

No compensation was provided to Professor Ian Hickie, Mr Tony Stevenson, Mental Illness Fellowship of Australia or Richard for this media announcement, and the opinions expressed are their own. Professor Hickie has been briefed by Seqirus on the approved use of this product.

## REFERENCES

1. The Pharmaceutical Benefits Scheme Medicine Status Website. CARIPRAZINE. 2021; Available from: <https://www.pbs.gov.au/medicinesstatus/document/16.html>.
2. Better Health Channel. Schizophrenia. [June 2021]; Available from: <https://www.betterhealth.vic.gov.au/health/ConditionsAndTreatments/schizophrenia>.
3. Health Direct. Schizophrenia. 2020 [June 2021]; Available from: <https://www.healthdirect.gov.au/schizophrenia>.
4. The Royal Australian & New Zealand College of Psychiatrists, *The economic cost of serious mental illness and comorbidities in Australia and New Zealand*. 2016.
5. Australian Government Productivity Commission, *Mental Health, Productivity Commission Inquiry Report*. 2020.
6. Schultz, S.H., S.W. North, and C.G. Shields, *Schizophrenia: a review*. Am Fam Physician, 2007. 75(12): p. 1821-9.
7. NeuRA. Positive symptoms. 2020 [June 2021]; Available from: <https://library.neura.edu.au/schizophrenia/signs-and-symptoms/general-signs-and-symptoms/positive-symptoms/>.
8. National Institute of Mental Health. Schizophrenia. 2020 [June 2021]; Available from: <https://www.nimh.nih.gov/health/topics/schizophrenia/>.
9. NeuRA. Negative symptoms. 2020 [July 2021]; Available from: <https://library.neura.edu.au/schizophrenia/signs-and-symptoms/general-signs-and-symptoms/negative-symptoms/>.
10. Approved Reagila Product Information. Available from: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-02598-1&d=202106291016933>.
11. The University of Queensland Australia. What are neurotransmitters? [August 2021]; Available from: <https://qbi.uq.edu.au/brain/brain-physiology/what-are-neurotransmitters>.
12. Therapeutic Goods Administration. Australian Public Assessment Report for Cariprazine hydrochloride. 2021 [May, 2021]; Available from: <https://www.tga.gov.au/sites/default/files/auspar-cariprazine-hydrochloride-210524.pdf>.
13. Laursen, T.M., M. Nordentoft, and P.B. Mortensen, *Excess early mortality in schizophrenia*. Annu Rev Clin Psychol, 2014. 10: p. 425-48.
14. Wildgust, H.J., R. Hodgson, and M. Beary, *The paradox of premature mortality in schizophrenia: new research questions*. J Psychopharmacol, 2010. 24(4 Suppl): p. 9-15.
15. World Health Organization (WHO). Schizophrenia. 2019 [June 2021]; Available from: <https://www.who.int/news-room/fact-sheets/detail/schizophrenia>.
16. Gil Dov Hoftman, M.D., Ph.D., *The Burden of Mental Illness Beyond Clinical Symptoms: Impact of Stigma on the Onset and Course of Schizophrenia Spectrum Disorders*. American Journal of Psychiatry Residents' Journal, 2016. 11(4): p. 5-7.
17. Reagila ARTG Summary. Available from: [https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=0C4BF80B7C892BC0CA258624003CC46E&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=0C4BF80B7C892BC0CA258624003CC46E&agid=(PrintDetailsPublic)&actionid=1).
18. Therapeutic Goods Administration. Reagila Consumer Medicine Information. Available from: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-CMI-02599-1&d=202107141016933>.