Australia's first pangenotypic hepatitis C treatment PBS listed, EPCLUSA® (sofosbuvir/velpatasvir)

New direct-acting antiviral treatment for all genotypes of chronic hepatitis C infection another step towards increased treatment access and potential disease elimination

Melbourne, Australia, 28 July 2017: The first pangenotypic direct-acting antiviral (DAA) agent, EPCLUSA® (sofosbuvir/velpatasvir), registered in Australia for the treatment of chronic hepatitis C (HCV) infection, will be available on the Pharmaceutical Benefits Scheme (PBS) from 1 August 2017.

EPCLUSA (sofosbuvir/velpatasvir) is the first, and currently the only, pangenotypic single tablet regimen with a uniform treatment duration of 12 weeks for the treatment of HCV genotypes 1–6 for patients with or without compensated cirrhosis, and in combination with ribavirin (RBV) for patients with decompensated cirrhosis.[1]

In clinical trials, 95 to 100 per cent of patients with HCV genotypes 1–6 taking a 12-week course of EPCLUSA achieved sustained viral response rates (SVR).[*1]

On 1 March 2016, Australia was the first country in the world to provide broad access to the new DAA regimens, and Australia has achieved one of the most rapid uptakes of treatment worldwide. Data from The Kirby Institute shows that between March 2016 and March 2017, an estimated 38,470 of Australia's estimated 230,000 people with HCV had been treated — representing almost 17 per cent of Australia's total HCV population.[2] While this initial uptake has been unprecedented, eliminating hepatitis C in Australia will require a significant increase in patients who are treated in primary care settings.

The Gastroenterological Society of Australia – Australian Liver Association (GESA–ALA) has stated that Australia is in a unique position where all people living with hepatitis C can access antiviral treatment and we have the potential to become one of the first countries in the world to eliminate hepatitis C as a public health threat, but only if treatment rates remain high.[3]

Professor Alex Thompson, Director, Department of Gastroenterology, St. Vincent's Hospital, Melbourne and Chair GESA–ALA, said that the PBS listing of EPCLUSA will help Australia to provide this opportunity for expanded treatment: “EPCLUSA allows simplified treatment for patients with all genotypes of chronic HCV infection, regardless of their treatment history or liver disease status.

"We hope that this will encourage people who have hepatitis C, including those living in regional and rural areas, to visit their local doctor for treatment.

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"The uniformity and simplicity of dosing with EPCLUSA, combined with the confidence of achieving high SVR rates, will help to achieve the higher treatment rates in community and general practice settings that Australia needs in order to continue its work towards eliminating hepatitis C."

EPCLUSA is Gilead's third sofosbuvir-based treatment to be registered in Australia for the treatment of chronic HCV infection, following HARVONI® and SOVALDI®. Sofosbuvir-based regimens are recommended by global guidelines across all HCV genotypes and liver disease severities.[4,5] Furthermore, the World Health Organization (WHO) added EPCLUSA to its Essential Medicines List on 6 June 2017, as the first combination therapy to treat all six types of hepatitis C.[6]

Gilead Sciences General Manager ANZ, Rob Hetherington, also welcomed news of the PBS listing:

"At Gilead, we are proud of the work that we do every day to ensure our medicines are widely available to Australians living with hepatitis C, and of the role these medicines can play in helping Australia eliminate the virus as a public health issue within our lifetime."

Minimum Product Information: EPCLUSA®

EPCLUSA (sofosbuvir/velpatasvir) 400/100 mg tablets. **INDICATIONS –** Chronic Hepatitis C (CHC) infection in adults. **DOSAGE AND ADMINISTRATION –** One tablet daily, orally for 12 weeks. Coadministration with ribavirin for patients with decompensated cirrhosis. **CONTRAINDICATIONS –** Hypersensitivity, concurrent use with other medicinal products containing any of the same active components. **PRECAUTIONS –** Symptomatic Bradycardia when coadministered with amiodarone, (coadministration is not recommended). Hepatitis B virus Reactivation. Use with Potent P-gp Inducers and/or Moderate to Potent CYP inducers. Pregnancy (Category B1 – EPCLUSA, Category X – Use with Ribavirin). If ribavirin is coadministered with EPCLUSA, the contraindications regarding use of ribavirin apply (refer to ribavirin PI). **DRUG INTERACTIONS –** Acid Reducing Agents, antiarrhythmics (amiodarone), anticonvulsants, antimycobacterials, antiretrovirals, St John's wort, HMG-CoA reductase inhibitors. **ADVERSE EFFECTS –**Headache, fatigue, nausea, and nasopharyngitis. This is not a full list – for more details/complete list of adverse events refer to full Product Information. **Full Product Information is available from Gilead Sciences Pty Ltd and should be reviewed before prescribing EPCLUSA.** 13 July 2017.

Please review the full Approved Product Information before prescribing. **The full EPCLUSA Product Information can be accessed here:**
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-PI-02886-1&d=2017011516114622483

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Footnotes and references

***Overall SVR12 rates for patients without cirrhosis or with compensated cirrhosis in clinical trials were 98% for GT 1, 100% for GT 2, 95% for GT 3, 100% for GT 4, 97% for GT 5 and 100% for GT 6.[1]**

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2. The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 7). The Kirby Institute, UNSW Sydney, Sydney, Australia, July 2017.
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For further information, please contact:
Andrea Ball 0417 815 689 or Tanya West 0406 907 84I5

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Notes to editors

Professor Alex Thompson has served on advisory boards for Gilead Sciences Australia.

About HCV and treatment with direct acting antivirals

Prior to the PBS listing of DAAs, chronic hepatitis C (HCV) infection affected an estimated 230,000 people in Australia.[9] It is the most common reason for liver transplantation in Australia[8] and a leading cause of liver cancer.[7] Since March 2016, the Australian Pharmaceutical Benefits Scheme (PBS) has funded direct-acting antiviral treatment. The vast majority of people with chronic hepatitis C remain at increased risk of serious liver disease without treatment. Sustained efforts to diagnose chronic hepatitis C and expand treatment coverage will be required to prevent this outcome.[9]

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercialises innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North and South America, Europe and Asia Pacific.

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