DRUG PROTECTION ALERT

Yentreve® last remaining SPC protection expires

Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) orignally developed by Eli Lilly in 1993 as an antidepressant. Duloxetine has since received market approval worldwide for treating conditions including neuropathic pain, generalised anxiety disorder and osteoarthritis among others, and many generics already exist on the market. In the US, it is currently the 48th most prescribed drug.[1] Eli Lilly received market approval in the UK in 2004 for treating Stress Urinary Incontinence (SUI)[2] with Duloxetine branded as Yeneve®.

August 2019 will bring the expiry of the last remaining SPCs for Duloxetine in certain European countries (Table 1). According to Ark Patent Intelligence, there are no other European patents or extensions which would constrain generic entry for the SUI indication after August 2019. The impact of this will be good news for patients in these countries, and generic companies will now be able to access these parts of Europe with their existing Duloxetine generics for treating SUI. Despite this, companies will still need to wait until expiry of the EP1113797 patent, in September 2020, to market Duloxetine generics for treating fibromyalgia.

Drug	Country
Duloxetine	Cyprus, Czech Republic, Lithuania, Latvia, Poland, Slovenia

Table 1: Molecules for which Supplementary Protection Certificates (SPCs) expire in certain markets in August 2019 (Source – Ark Patent Intelligence)

August 2019 will also see the data exclusivity expiry for Repatha® (Evolocomab) in the USA (Table 2). Repatha is a monoclonal antibody drug which inhibits the PCSK9 enzyme and is used to treat high cholesterol alongside statins or where statins are ineffective. Repatha is marketed by Amgen and approved in over 60 countries. The drug has been involved in patent litigation in the US since 2014, involving Sanofi and Regeneron's Praluent® (Alirocumab), a competing PCSK9-inhibiting antibody; in February 2019 the federal jury in the District of Delaware upheld validity of Amgen's patents (US8829165 and US8859741) covering Repatha and more recently, in July 2019, Amgen successfully blocked Sanofi from marketing Praluent in Germany due to infringement.

Despite being launched as a potential blockbuster, Repatha did not perform as well as expected and subsequently Amgen reduced the price of the drug by 60% in 2018.[3] This move should have helped make the drug more affordable to patients in the US as although the Biosimilar Application Submission Exclusivity (BASE) is expiring in August 2019, no biosimilar of Evolocomab will be approved untill August 2027 because of the validity of the Biosimilar Application Approval Exclusivity (BAAE) in the US on Evolocumab.

Drug	Country
Acetylsalicylic Acid, Esomeprazole	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, Great Britain, Greece, Croatia, Hungary, Ireland, Israel, Italy, Lithuania, Luxembourg, Latvia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia
Dabrafenib	Turkey
Eliglustat	US
Empagliflozin	US
Empagliflozin, Linagliptin	US
Empagliflozin, Metformin	US
Evolocumab[1]	US
Fenofibrate, Simvastatin	Turkey
Lacosamide	Switzerland
Linagliptin	European Union
Lomitapide	Turkey
Mva-Bn	Turkey
Naltrexone, Oxycodone	US
Ocriplasmin[2]	Canada
Oritavancin[3]	US
Pomalidomide	Turkey
Regorafenib	Korea
Retapamulin	Switzerland
Rifaximin[2]	Canada
Suvorexant	US
Teriflunomide	Turkey

[1] This will be followed by 8 years of biosimilar application approval exclusivity, during which a biosimilar will not be approved.

[2] This will be followed by a no-marketing period of two years during which a notice of compliance will not be granted to a generic manufacturer.

[3] This will be followed by five years of GAIN (Generating Antibiotic Incentives Now) exclusivity

Table 2: Molecules for which data exclusivity expires in certain markets expire in certain markets in August 2019 (Source – Ark Patent Intelligence)

Ark Patent Intelligence is produced by IQVIA™, a global provider of intelligence for the pharmaceutical sector. To find out more, please visit https://www.iqvia.com/our-customers/generics-manufacturers/ark-patent-intelligence

1. https://clincalc.com/DrugStats/Top300Drugs.aspx
2. https://www.ema.europa.eu/en/medicines/human/EPAR/yentreve
3. https://www.amgen.com/media/news-releases/2018/10/amgen-makes-repatha-evolocumab-available-in-the-us-at-a-60-percent-reduced-list-price/