1. RWE data used to highlight drug effectiveness and safety for patients switching to a biosimilar

Hospira's inflectra (infliximab biosimilar) at EULAR 2015

Hospira's survey of 10 patients switching from infliximab to its biosimilar INB (for rheumatoid arthritis) showed effectiveness was the same/similar for patients who switched, with no immediate safety signals over a median 11 month period. Presented at EULAR and got considerable attention amidst a very competitive landscape. Other infliximab biosimilars (Celltrion's CT-P13 and EPIRUS'S BDMO15) also presented (non-RWE) data at EULAR.

Link to Abstract

2. RWE bridging data gaps for a new diabetes drug class & strengthening the clinical trial dataset

AstraZeneca's Forxiga (Dapagliflozin) published in the British Journal of Diabetes and Vascular Disease

AstraZeneca's survey of 938 patients who switched from Infliximab to its biosimilar was to assess real-world CZP utilisation and costs. The results demonstrate that adverse effects are more common in real-world clinical practice compared to clinical trials.

Link to Journal Publication

3. RWE data showing a statistically significant decrease in the number of hospital admissions/ bed days leading to a successful NICE submission

Norgine's Targaran (Rifaximin) NICE Appraisal 2015

As part of their successful NICE submission [TA337], Norgine submitted RWE from clinical audit data of rifaximin use at 4 centres in the UK and carried out a meta-analysis of the data. The data showed that treatment with rifaximin was associated with statistically significant decreases in the number of hospital admissions and the number of bed days, compared with treatment without rifaximin.

Link to News Article
Link to NICE Guideline

4. RWE data used to demonstrate the usage and cost savings of a drug’s patient access scheme to the NHS

UCB's Clinica (Entolirumab Pegil) at ISPOR 2014

UCB's Clinica (Entolirumab Pegil) was published in the British Journal of Rheumatology clinics. CDP cost for 52 weeks therapy was £30,368 per patient in England/Wales and £6,793 with the 12 weeks for free PAS applied. This is £2,502 and £2,363 less than comparable annual per patient costs for etanercept and adalimumab, respectively. Presented at ISPOR 2014.

Link to Abstract

5. RWE demonstrating the real-life impact of a widespread but poorly understood problem

AstraZeneca's survey of the impact on adults influenza like illness (ILI) in children at ISPOR 2014

AstraZeneca and Patients Direct designed and implemented a survey of 938 households. Based on the survey, approximately 1/3 of adult ILIs were related to prior household child ILI. ILI in a household often required absence from work and 1/2 in children often resulted in time off education. GP visits were the most frequent burden to the NHS. This data was presented at ISPOR 2014.

Link to Scientific Poster
6. Upcoming RWE study of 550 patients designed to collect patient experience and real world outcomes

Upcoming PROSPER Study 2015
In 2015 Norgine announced the study design of their real world evidence study, PROSPER. This will be a large observational multicentre study of 550 patients, which they describe as a real world outcomes study of hepatic encephalopathy patients' experiences.

Link to Press Release
5. RWE data from safety and QoL studies used to revise economic model leading to a successful HTA re-submission
Sanofi’s Zaltrap (Aflibercept) SMC re-submission
In June 2013, the SMC reviewed Zaltrap in combination with FOLFIRI chemotherapy for the treatment of adults with metastatic colorectal cancer. The SMC evaluated one randomised, placebo-controlled phase III study and, despite demonstrating significantly longer overall survival, Zaltrap was not recommended because of the lack of a sufficiently robust economic analysis. In a February 2014 resubmission, Sanofi included two open-label Real World Evidence studies assessing safety and quality of life. This RWE was used to revise the utility values within the economic model. SMC recommended Zaltrap because the new data demonstrated a substantial improvement in QoL. In addition, Sanofi also presented a patient access scheme, which improved the cost-effectiveness evaluation of Zaltrap.

Link to News Article
Link to SMC Appraisal

6. RWE showing improved symptoms and decreased resource utilisation enabling successful HTA re-submission
Gilead’s Cayston (Aztreonam Lysine) SMC re-submission 2014
Gilead and SVMPharma developed an online Real World Treatment Evaluator for the cystic fibrosis drug Cayston, to assess its effectiveness in routine practice across several centres. Data was collected for up to 1 year pre- and post-Cayston use and showed that the introduction of the drug significantly improved lung function, weight, hospitalisation, and exacerbation rates.

This study was presented at European Cystic Fibrosis Society in 2014 and the data enabled Gilead to re-submit successfully to the SMC.

Link to Abstract
Link to SMC Appraisal

7. RWE showing positive clinical and patient outcomes for fixed-dose combination (FDC) drug
Napp’s Targinact at British Pain Society ASM 2015
Napp and SVMPharma developed a RWE data collection program in 13 sites across the UK and Ireland to obtain data on the effectiveness of oxycodone/naloxone in patients suffering from opioid-induced constipation (OIC), despite the use of laxatives (or for patients who are unable to tolerate laxatives owing to side-effects).

The results showed that fixed-dose oxycodone/naloxone reduced symptoms of constipation, improved quality of life, and reduced laxative use in patients with OIC. This was despite a challenging patient group, with many patients having previously failed on laxatives, and most having several additional factors contributing to their constipation.

This data was presented at the British Pain Society ASM 2015.

Want to learn more about generating Real World Evidence?
contact SVMPharma enquiry@svmpharma.com

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