ORIGINAL RESEARCH
Economic Evaluation

Cost-Effectiveness Evaluation in Sweden of Escitalopram Compared with Venlafaxine Extended-Release as First-Line Treatment in Major Depressive Disorder

Göran Nordström, PhD1, Natalya Danchenko, PhD2*, Nicolas Despiegel, MSc1, Florence Marteau, MSc2
1Psychiatriska kliniken, Huddinge Trelleborg, Sweden; 2Lundbeck SAS, Issy-les-Moulineaux Cedex, France; 3Innovus, Nanterre, France

ABSTRACT

Objectives: Major depressive disorder (MDD) is a major public health concern associated with a high burden to society, the health-care system, and patients and an estimated cost of €3.5 billion in Sweden. The objective of this study was to assess the cost-effectiveness of escitalopram versus generic venlafaxine extended-release (XR) in MDD, accounting for the full clinical profile of each, adopting the Swedish societal perspective, and identifying major cost drivers.

Methods: Cost-effectiveness of escitalopram versus venlafaxine XR was analyzed over a 6-month time frame, on the basis of a decision tree, for patients with MDD seeking primary care treatment in Sweden. Effectiveness outcomes for the model were quality-adjusted life-years and probability of sustained remission after acute treatment (first 8 weeks) and sustained for 6 months. Cost outcomes included direct treatment costs and indirect costs associated with sick leave.

Results: Compared with generic venlafaxine XR, escitalopram was less costly and more effective in terms of quality-adjusted life-years (expected gain 0.00865) and expected 6-month sustained remission probability (incremental gain 0.0374). The better tolerability profile of escitalopram contributed to higher expected quality-adjusted life-years and lower health-care resource utilization in terms of pharmacological treatment of adverse events (though only a minor component of treatment costs). Expected per-patient saving was €169.15 for escitalopram versus venlafaxine. Cost from sick leave constituted about 85% of total costs.

Conclusions: Escitalopram was estimated as more effective and cost saving than generic venlafaxine XR in first-line MDD treatment in Sweden, driven by the effectiveness and tolerability advantages of escitalopram. The study findings are robust and in line with similar pharmacoeconomic analyses.

Keywords: cost-effectiveness, first-line therapy, major depressive disorder (MDD), remission, selective norepinephrine reuptake inhibitor (SNRI), selective serotonin reuptake inhibitor (SSRI).

Background

Globally, major depressive disorder (MDD) is a major public health concern associated with a high burden to society, health-care system, and patients. In Sweden, the estimated cost of depression doubled between 1997 and 2005, from €1.7 to €3.5 billion [1]. This cost increase was primarily driven by an increase in indirect costs associated with sick leave and early retirement, over the past decade, whereas direct costs remained relatively stable over time [1].

The pharmacological treatment options in MDD include selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors. In a meta-analysis, venlafaxine, a serotonin norepinephrine reuptake inhibitor, has been shown to be more effective than traditional SSRIs [2]. Escitalopram, the S enantiomer of citalopram, is the most selective SSRI available [3]; in recent clinical studies, escitalopram was shown to be at least as efficacious as venlafaxine extended-release (XR), but with a better tolerability profile [4-7].

Clinical efficacy and tolerability are the first considerations when choosing an antidepressant drug (AD), but consideration of cost is also becoming increasingly important. Several cost-effectiveness (CE) studies of escitalopram versus venlafaxine XR have shown that the clinical advantages of escitalopram translate into benefits in real-life effectiveness: reduction in sick leave and health-care resource utilization (outpatient and inpatient care, pharmacological treatment, etc.) and associated costs [8-12]. These CE studies, however, tended to focus on efficacy without considering the impact of tolerability on quality of life. In addition, in countries such as Sweden, where a generic formulation of venlafaxine XR has recently become available, the CE of escitalopram versus venlafaxine XR needs to be re-evaluated.

In Sweden, with a single-payer health-care system and a strong health technology assessment outlook, adequate up-to-

* Address correspondence to: Natalya Danchenko, Lundbeck SAS, 37–45 Quai du Président Roosevelt, 92445 Issy-les-Moulineaux Cedex, France.
E-mail: NADO@Lundbeck.com
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date evidence of CE is essential for decision making. The object- describe the perspective in Sweden, and identifying the major cost drivers associated with the management of depression.

Methods

A CE analysis of escitalopram versus venlafaxine XR was conducted over a 6-month time frame from the societal perspective, based on a decision tree. In this model, escitalopram was compared with generic venlafaxine XR, an AD of the serotonin norepinephrine reuptake inhibitor class. Both ADs are reimbursed for the treatment of depression in Sweden [13], and the market share of venlafaxine is expected to increase since it became generic in Sweden in 2009. The target population consisted of adult patients (aged 18–65 years) with moderate to severe MDD seeking treatment in a primary care setting in Sweden, consistently with underly- ing clinical data. The effectiveness outcomes for the model were quality-adjusted life-years (QALYs) and the probability of sustained remission, defined as a remission (Montgomery Åsberg Depression Rating Scale score ≤12) achieved during acute treatment (first 8 weeks of treatment) and sustained until the end of the 6-month time frame. Cost outcomes included direct treatment costs (ambulatory care, hospitalizations, pharmacological therapy [AD use accounting for titration; treatment of adverse events, AEs]) and indirect costs associated with sick leave.

Model structure

A decision analytic model was created by using a previously published model of escitalopram versus sertraline [14], modified to reflect clinical practice patterns associated with the use of escitalopram and venlafaxine in the treatment of MDD in Sweden, based on newly available data, including long-term relapse data (i.e., relapse in patients who had achieved remission). The decision tree is presented in Figure 1. The 6-month time frame for the model, common for economic evaluations of ADs [15,16], was chosen to capture the largest proportion of clinical events within a given depressive episode (remission, AEs, relapses) but without being too long that extrapolations beyond the available clinical and real-life data would jeopardize the accuracy of the model. This time frame also limited the number of assumptions and the number of pathways (the overall structure) within the model. To populate the model, clinical trial data over 8 weeks were used, supplemented as much as possible by data from the country-specific real-life study HEADIS (a naturalistic longitudinal Swedish survey) [14]. The initial 2-month acute treatment was assumed to start with either 10 mg escitalopram or 75 mg venlafaxine XR, with a possible dose adjustment during the second month (to escitalopram 20 mg/d or venlafaxine 150 mg/d, respectively), in line with the dose recommendations for both products, according to the Summary of Product Characteristics. During this acute treatment period, patients could achieve remission of symptoms (Montgomery Åsberg Depression Rating Scale score ≤12). Patients who achieved remission during this period were assumed to continue medication for a 4-month maintenance period. During this maintenance treatment, patients could relapse or remain in remission (sustained remission). Patients who did not achieve remission during the 8 weeks of initial therapy either switched to another AD or stopped the treatment prematurely (based on real-life practice assessed as detailed below).

The results of the analysis were estimated on the basis of utilities and costs associated with different health states (as detailed below). The model was run as a Monte Carlo simulation comprising 10,000 iterations, resulting in 95% credibility intervals of point estimates of incremental costs and effectiveness (QALYs and probability of sustained remission) for escitalopram versus venlafaxine.

The model was developed by using Data 4.0 software (TreeAge Software, Inc., Williamstown, MA).

Data sources and model assumptions

Clinical inputs

The clinical inputs for remission, AEs, and relapse probabilities for each treatment arm are shown in Table 1. The 8-week remission probabilities were derived from a pooled analysis of two randomized controlled trials (RCTs) of venlafaxine and escitalopram [7].

Fig. 1 - Cost-effectiveness model of escitalopram or venlafaxine extended-release for major depressive disorder in Sweden: 1) The venlafaxine arm is a clone of the escitalopram arm (implying the same structure). 2) Sustained remission at 6 mo: patients who achieved remission at week 8 since treatment initiation and remaining in remission by week 24. Patients were expected to continue on the same medication for another 4 mo (maintenance therapy). 3) Relapse at 6 mo: Patients who achieved remission at week 8 since treatment initiation but subsequently relapsed. 4) Premature stop at 8 wk: Patients who did not achieve remission during the first 8 wk of therapy and stopped medication. 5) Switch at 8 wk: Patients who did not achieve remission during the first 8 wk of therapy and switched to another medication. 6) The model was developed by using Data 4.0 software (TreeAge Software, Inc., Williamstown, MA). AD, antidepressant drug; Esc, escitalopram; MDD, major depressive disorder.
The probability of sustained remission over the total 6-month time frame was estimated from the naturalistic longitudinal Swedish survey HEADIS [14], capturing data for patients with depression in 56 primary care centers in Sweden who were initiating a new AD therapy or changing ongoing therapy. The probabilities of sustained remission were based on physician judgment as documented in the HEADIS and were not treatment specific due to the small number of patients reporting sustained remission. The 6-month relapse probability for patients who achieved remission over the initial 8 weeks of treatment was estimated as complementary to the switch probability of stopping treatment because of nonresponse to the acute treatment, on the basis of other placebo-controlled studies showing that the probabilities of relapse are relatively similar [17-20].

Because of data limitations, the model accounted for occurrence of AEs during the first 2 months of treatment only, using the data on treatment-specific probabilities of AEs from the same pooled analysis [7]. Only those AEs that occurred in at least 7% of the patients in any treatment arm in the pooled analysis were included in the model (the 7% cutoff allowed selection of relevant and meaningful AEs).

### Treatment patterns

As mentioned above, this model assumed initiation of an AD therapy with the usual initial dosing of 10 mg escitalopram and 75 mg venlafaxine as recommended in the Summary of Product Characteristics. A possible need for a dose adjustment during the acute treatment was expected in the model as a treatment-specific probability of titration (to 20 mg/d escitalopram or 150 mg/d venlafaxine, respectively) in the second month of treatment, with probabilities based on the HEADIS data (Table 1) [14].

The probability of switch in case of nonresponse to the initial 8-week treatment was estimated on the basis of HEADIS data as complementary to the probability of sustained remission. The relapse probabilities were assumed to be the same irrespective of the treatment, on the basis of other placebo-controlled studies showing that the probabilities of relapse are relatively similar [17-20].

Because of data limitations, the model accounted for occurrence of AEs during the first 2 months of treatment only, using the data on treatment-specific probabilities of AEs from the same pooled analysis [7]. Only those AEs that occurred in at least 7% of the patients in any treatment arm in the pooled analysis were included in the model (the 7% cutoff allowed selection of relevant and meaningful AEs).

### Utilities

Utilities associated with remission, treatment stop, and switch were taken from the HEADIS data, assessed by using the EuroQoL five-dimensional scale (Table 2). Over the 6-month time frame, utilities specific to each treatment outcome were calculated as follows. Remitted patients on maintenance therapy were assumed to have the average of baseline and remission utility over the first 8 weeks and the utility associated with remission for the remaining 16 weeks. Nonremitting patients switching after the first 8 weeks were assumed to have the average of baseline and utility related to switch over the 8 first weeks of medication and the utility associated with switch for the remaining 16 weeks (similar calculation applied for nonremitting patients stopping treatment, but applying utility related to treatment stop).

Patients with AEs were assumed to have a decrement in utility associated with the AEs over the first 8 weeks; these AE-related utility decrements were derived from a published economic model in depression [16], originally based on the 2000 Medical Expenditure Panel Survey [21].

### Resource utilization

Six-month resource use associated with different health states/treatment outcomes (remission vs. switch or stop of treatment in case of nonremission) was estimated from HEADIS [14] (Table 2), including hospitalization (number of bed days) and ambulatory care (general practitioner [GP], specialist, nurse, psychologist/therapeutic, counselor, and emergency visits). It was assumed that patients titrated to a higher dose needed an additional GP visit, and the number of such additional visits per patient was assumed to be equal to the estimated average number of titrations per patient in patients who had up-titration (in the period before a switch in medication in the HEADIS study).

### Medication

In the present model, estimation of pharmacological medication use was based on prescriptions for ADs and AE-related medication. AD use accounted for a switch option after 8 weeks of initial treatment; for patients who switch, the AD cost over the last 4-month period was based on the average of the four most commonly prescribed ADs based on IMS data to April 2009 (IMS Midas, April 2009).

Medications to treat AEs were identified by two Swedish medical experts. The cost of treatment for an AE was assumed to be the price of the lowest package of medication and was taken from The Dental and Pharmaceutical Benefits Agency (Tandvårds Och Läke-
The estimated average 6-month overall cost was €7,377.89 per patient for escitalopram and €7,547.04 per patient for venlafaxine. Consequently, the expected per patient saving was €169.15 per patient for escitalopram versus venlafaxine.

Cost from sick leave constituted the major component of the overall cost, at about 85% in both treatment arms. For direct treatment costs, the highest proportion was due to GP visits.
The robustness of the observation that escitalopram was less costly and more effective in terms of QALYs gained (utilities) and the expected probability of sustained remission was tested in a Monte Carlo simulation of 10,000 iterations (i.e., patients), resulting in a 62.2% probability that escitalopram was the dominant therapy (Fig. 2). The CE acceptability curve from the Monte Carlo simulation is presented in Figure 3, showing that with a willingness to pay of €22,080 and €33,600 per QALY gained, escitalopram had 78.4% and 82.3% probability, respectively, of being cost-effective compared with venlafaxine (Fig. 3).

One-way sensitivity analyses
Sensitivity analyses found that the decision analytic model was most sensitive to the escitalopram remission probability. In the base case, the escitalopram remission probability (8 weeks) was 0.621, producing a difference of 0.00865 and –€169.15 per patient in terms of expected QALYs and expected cost, respectively, compared with venlafaxine. When the remission probability with escitalopram was decreased to the lower limit of the confidence interval (0.559), the incremental QALY decreased to 0.0009 and the incremental overall societal cost with escitalopram versus venlafaxine increased to €96.48 per patient (Table 5).

Because costs associated with sick leave were a major contributor to overall costs, the model was tested on robustness to the number of sick-leave days. Varying this parameter (sick leave associated with remission, switch, and stop of treatment) over the 95% confidence limits had an impact on the expected per-patient cost, but escitalopram remained a cost-saving therapy compared with venlafaxine (Table 5).

Likewise, the conclusions on cost savings associated with escitalopram versus venlafaxine XR did not change by varying the number of GP visits, the major driver of direct costs.

Finally, the sensitivity analysis was performed on the incidence of nausea, the AE with the greatest impact on QALYs. Variation of this input parameter around the confidence limits resulted in corresponding changes in QALYs without changing the conclusions of the base-case analysis regarding the greater effectiveness of escitalopram versus venlafaxine.

Conservative scenario analysis
In the conservative analysis (assuming that generic venlafaxine XR will cost 5% of branded venlafaxine), escitalopram remained dominant to venlafaxine XR, with an incremental effectiveness similar to that of the base case and cost savings of –€76.80 per patient from a...
societal perspective. When considering a willingness to pay of €22,080 and €33,600 per QALY gained, in the conservative analysis escitalopram still had 67.8% and 74.4% probability, respectively, of being cost-effective compared with venlafaxine XR from a societal perspective. In the same conservative scenario, accounting for direct costs only, escitalopram was associated with an estimated incremental per-patient cost of €76.51 (and still the same gain in QALYs).

Discussion

This was the first CE analysis comparing escitalopram with the generic venlafaxine. The results showed that compared with generic venlafaxine XR, escitalopram was less costly and more effective in terms of QALYs and an expected 6-month sustained remission probability. The better tolerability profile of escitalopram compared with that of venlafaxine contributed to higher expected QALYs and lower health-care resource utilization in terms of pharmacological treatment of AEs (though only a minor component of treatment costs).

The results from two randomized, multicenter, double-blind, 8-week studies that compared the efficacy and tolerability of escitalopram and venlafaxine XR [4,5] were used as data sources both in the pooled analysis used as the basis for clinical inputs in this economic analysis [7] and in the more recently published Cochrane review of escitalopram [22]. Although the escitalopram Cochrane review was unpublished at the time this analysis was carried out, the outcomes from these two different comparisons of escitalopram and venlafaxine XR are consistent with regard to both efficacy and tolerability. Specifically, the review found no evidence that escitalopram was more or less efficacious than venlafaxine in all parameters reported (i.e., proportion of patients who responded to treatment after 6–12 weeks or early response [1–4 weeks], proportion of patients who achieved remission after 6–12 weeks, and mean change from baseline in measures of de-
pressive symptoms) and that there was no evidence that escitalopram was associated with a lower rate of AEs than venlafaxine, besides nausea and increased sweating [22].

The economic model results were shown to be most sensitive to changes in escitalopram remission. In addition to one-way sensitivity analyses of these inputs, Monte Carlo analyses that varied the probability of remission for both treatments simultaneously (along with a number of other parameters) were carried out. These analyses also showed a high probability that escitalopram was a cost-effective treatment option.

Cost from sick leave constituted about 85% of the total costs. Therefore, the benefit of escitalopram in terms of sick-leave reduction was a major driver of the overall cost savings compared with venlafaxine XR. The cost of outpatient care/physician visits accounted for a major proportion of the direct costs; hence, decreasing the number of physician visits because of improved treatment effectiveness and reduced frequency of AEs (requiring additional health-care resource consumption) resulted in savings in direct costs, in addition to improved productivity and reduction in associated indirect costs.

The model was robust to variation of the key input parameters. In the current analysis, AD treatment cost constitutes only a minor portion of the direct treatment costs (and only 1.46%–2.00% of the total costs); even with the conservative assumption of venlafaxine unit cost amounting to 5% of the branded price, escitalopram remained a dominant treatment option compared with venlafaxine.

These results are in line with findings from other pharmacoeconomic studies comparing escitalopram with venlafaxine XR. In the model by Sullivan et al. [16], also accounting for both effectiveness and tolerability advantages of escitalopram versus venlafaxine XR, escitalopram was associated with an incremental QALY of 0.005 per patient and a cost saving equivalent to €502.50 compared with venlafaxine XR for initial treatment over 6 months. The exchange rate used was that for December 1, 2009 (€1 = US$0.66); costs were calculated to two decimal places (http://www.ecb.europa.eu/stats/eurofxref/eurofxref-hist-90d.xml) [16]. Other studies driven by effectiveness but not accounting for tolerability impact on health-related quality of life also reported economic advantages of escitalopram versus venlafaxine. In the economic model by Kulp et al. [12], savings per treatment responder with escitalopram versus venlafaxine amounted to €43 under GP and €58 under specialist treatment (equivalent to 34% and 42%), respectively. In other decision-analytic modeling studies using indirect comparative clinical trial data, escitalopram was cost saving versus SSRIs and venlafaxine [8-10,23-25]. In the prospective analysis by Fernandez et al. [11] comparing escitalopram and venlafaxine XR based on direct clinical comparative data alongside an international clinical trial, after adjustment for key baseline factors, escitalopram was associated with 40% lower direct health-care costs than venlafaxine XR (95% confidence interval 10–81; P = 0.007). In that study, indirect costs due to sick leave accounted for at least 80% of the total cost in both treatment arms. It should be noted, however, that previous analyses did not consider generic venlafaxine.

Limitations
As with any pharmacoeconomic modeling analysis, there are limitations to this model. For instance, bias may be present because of compiling data from different sources; specifically, the remission and relapse data are derived from RCTs and the HEADIS data set, respectively. The advantage of the observational HEADIS data, however, is the specificity to Sweden and reflection of the local practice patterns, allowing the assessment of real-life effectiveness and economic implications of efficacy and tolerability benefits of the drug beyond the conditions of RCTs. In addition, the patient population was comparable between the two data sources: the RCTs focused on patients with an episode of MDD, while 75% of the patients in the HEADIS data set were defined as moderately or severely ill.

The use of a 6-month time frame may be a limitation of this model, given the chronic nature of MDD and the likelihood of the need for long-term treatment. The choice of this time frame was a balance between accurately reflecting the clinical pathway and appropriately using the available data, but a longer time perspective may alter the conclusions. This is a common challenge, and
many economic analyses in MDD have used a 6-month time frame [15,16]. A probabilistic Markov cost-utility analysis has also demonstrated escitalopram dominance over duloxetine over a 1-year time horizon [26]. Further longer-term prospective economic studies or modeling analyses, however, are needed to document how the cost benefits achieved with escitalopram versus venlafaxine are maintained over the longer term.

Another limitation was a scarcity of data sources, requiring some assumptions about input parameters. For instance, AEs were modeled only over the first 8 weeks, conservatively assuming no difference in the probabilities of AEs between treatment arms for the subsequent 4 months. With the clinical evidence that most AEs occur early in the course of treatment, however, this assumption is unlikely to have an impact on the conclusions of the analysis. The model also assumed no additional resource use for AEs beyond drugs to treat the AEs; however, this assumption is justified with generally mild-level severity of the AEs associated with SSRIs, typically not associated with other health-care resource use. Another assumption was a similar probability of relapse between the treatment arms, justified by the observations in clinical studies of the two drugs [17-20].

Finally, the model accounted only for major treatment patterns based on the HEADIS data, such as titration or treatment discontinuation in case of nonresponse to the acute 8-week treatment, not accounting for other options such as augmentation. This potential limitation is justified with the HEADIS data source being specific to Sweden and hence reflects local treatment patterns [14].

A variety of different modeling approaches can and have been used in depression. Previous publications have also used a decision analytic model [15,16] and, in this case, the analysis based on a decision-tree model was also related to the choice to keep a simple framework, which was supported by real-life data requiring fewer assumptions.

Several sensitivity analyses demonstrated that the model results were robust to potential uncertainties and assumptions. Furthermore, the economic benefits of escitalopram reported in this analysis may be conservative because the model did not incorporate other known advantages of escitalopram. For instance, a significantly faster onset of remission with escitalopram versus venlafaxine [4] might potentially be associated with additional savings in direct treatment costs and savings related to a faster reduction in sick leave. In addition, because of data scarcity, the model conservatively assumed no additional visits to the physician associated with the treatment of AEs; this might result in underestimation of cost savings associated with tolerability benefits of escitalopram compared with venlafaxine.

In the current health-care environment, important challenges are arising in clinical and health economics evaluations and further research is needed to build on the analyses presented in this article. In particular, treatments are becoming increasingly tailored to selected patient groups rather than the broader disease population, allowing health-care decision makers to reduce uncertainty, improve care, and enhance the efficiency of health-care resource utilization [27]. Therefore, CE evidence increasingly needs to be focused on specific patient populations. This requires new clinical and observational studies to provide robust underlying data regarding different patient subgroups with MDD, which can be used for future more targeted economic evaluations.

### Table 5 – Results from one-way sensitivity analyses (costs in € 2009).

<table>
<thead>
<tr>
<th>Base-case value</th>
<th>Outcome</th>
<th>Sensitivity analyses values</th>
<th>Outcomes (mean)</th>
<th>Incremental sensitivity analyses</th>
<th>Incremental base-case analyses</th>
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<tbody>
<tr>
<td>Remission probability (8 wk)</td>
<td>62.1%</td>
<td>55.9%</td>
<td>Total costs</td>
<td>96.48</td>
<td>169.15</td>
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<td></td>
<td></td>
<td></td>
<td>QALYs</td>
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<td>0.0087</td>
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<td></td>
<td>68.1%</td>
<td>61.5%</td>
<td>Total costs</td>
<td>–411.55</td>
<td>169.15</td>
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<td></td>
<td></td>
<td></td>
<td>QALYs</td>
<td>0.0162</td>
<td>0.0087</td>
</tr>
<tr>
<td>Sick leave (number of days)</td>
<td>Remission</td>
<td>38.45</td>
<td>29.52</td>
<td>Total</td>
<td>–2206</td>
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<td></td>
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<td>47.38</td>
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<td></td>
<td>Switch</td>
<td>57.88</td>
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<td>Total</td>
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<td></td>
<td>69.98</td>
<td>Total</td>
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<td>GP visits (number)</td>
<td>Remission</td>
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<td>Total</td>
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<td></td>
<td>6.53</td>
<td>Total</td>
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<td>1762</td>
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<tr>
<td>Probability (8 wk) of nausea with escitalopram</td>
<td>12.7%</td>
<td>8.9%</td>
<td>Total</td>
<td>–1705</td>
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<td>QALYs</td>
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<td>QALYs</td>
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GP, general practitioner; QALY, quality-adjusted life-years.
Conclusions

Escitalopram is more effective and cost saving compared with generic venlafaxine XR in the first-line treatment of MDD in Sweden. These benefits are driven by the effectiveness and tolerability advantages of escitalopram, resulting in improved health-related quality of life and probability of sustained remission and lower health-care resource utilization and sick leave. The reduction in indirect costs due to sick leave is the major driver of savings in overall costs. These findings are robust and are maintained even in a conservative analysis in which the cost of generic venlafaxine XR is 5% of the branded version of the drug. The results of this analysis are inline with other pharmacoeconomic analyses comparing escitalopram with venlafaxine.

Acknowledgments

The authors acknowledge Mary Gabb (Rx Communications, UK) and Jan McKendrick (Rx Communications, UK) for medical writing assistance in the preparation of this article. Additional project management and editorial support was provided by Rx Communications, UK.

Source of financial support: This study was supported by Lundbeck SAS. Göran Nordström received honoraria from Lundbeck SAS for his contribution to work on this manuscript. Natalyia Danchenko and Florence Marteau are employees of Lundbeck SAS. Nicolas Despiegel was an employee of Lundbeck SAS at the time of the study and the development of this manuscript. All the authors have nonfinancial competing interests. Göran Nordström participated in the design of the study and manuscript preparation, ensuring relevance of the model and interpretation of findings to the context of the clinical setting in Sweden. Natalyia Danchenko participated in the design of the study and interpretation of findings, drafted the manuscript, and finalized it according to coauthors’ and reviewers’ comments. Nicolas Despiegel participated in the design of the study and interpretation of findings, drafted the manuscript, and helped to draft the manuscript. All authors read and approved the final manuscript.

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