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PHARMACOECONOMIC ASSESSMENT OF NATALIZUMAB IN THE TREATMENT OF MULTIPLE SCLEROSIS

Matveev NV¹, Sabanov AV²¹Nicomed Russia, Moscow, Russia, ²Volgograd State Medical University, Volgograd, Russia

OBJECTIVES: In Russia, over 100,000 patients are diagnosed with multiple sclerosis (MS), but only about 18,000 patients are on disease modifying therapy (DMT) (Gusev El et al, 2011). Introduction of new DMT, such as natalizumab, requires a pharmacoeconomic substantiation, to prove its cost-effectiveness in Russian economic conditions. **METHODS:** Cost-effectiveness of natalizumab treatment was compared to that of interferon beta-1a IM, interferon beta-1a SC, interferon beta-1b, and glatiramer acetate, using the cost of an avoided relapse. **RESULTS:** The cost of 12-month treatment with natalizumab is 1,186,176 RUB (37,608 USD), the 12-month costs of treatment with interferon beta-1a IM, interferon beta-1a SC, interferon beta-1b, and glatiramer acetate were 459,534 RUB, 797,940 RUB, 532,080 RUB, and 502,073 RUB respectively, using average prices for 2010-2011 (or 14,570 USD, 25,299 USD, 16,870 USD, 16,014 USD). Despite higher cost of course of natalizumab, its efficacy was higher compared to other DMT. Annual number of avoided relapses per one patient with relapsing-remitting MS on natalizumab was 1.27 (Polman CH, et al. 2006). At the same time, for comparable groups of MS patients treated with interferon beta-1a IM, interferon beta-1a SC, interferon beta-1b, and glatiramer acetate, the numbers of prevented relapses were 0.61, 0.65, 0.55, and 0.61 respectively (Jacobs LD, et al., 1996; PRISMS Study Group, 1998; The IFNB MS Study Group, 1993; Johnson KP, et al., 1995). The calculated costs of one prevented relapse was 934,000 RUB (29,613 USD) for natalizumab, 753,000 RUB for interferon beta-1a IM (23,885 USD), 1,227,000 RUB (38,922 USD) for interferon beta-1a SC, 967,000 RUB (30,672 USD) for interferon beta-1b, and 823,000 RUB (26,096 USD) for glatiramer acetate. **CONCLUSIONS:** The cost of one prevented relapse in patient treated with natalizumab was lower than in patients treated with interferon beta-1a SC and interferon beta-1b, but somewhat higher than in patients treated with interferon beta-1a IM and glatiramer acetate.

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ECONOMIC EVALUATION OF NATALIZUMAB VERSUS FINGOLIMOD FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS IN SWEDEN

Alexopoulos ST¹, Deniz B², Walker AR¹, Arnold R², Bates D³¹Heron Evidence Development, Ltd., Luton, Bedfordshire, UK, ²Biogen Idec, Weston, MA, USA,³The Royal Victoria Infirmary, Newcastle upon Tyne, Tyne and Wear, UK

OBJECTIVES: Fingolimod has recently been approved for reimbursement in Sweden for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS). Based on its indication, fingolimod will be a new alternative for patients with RRMS (the population for which natalizumab is also indicated). The objective is to evaluate the cost-effectiveness of natalizumab compared to fingolimod in patients with RRMS and a sub-group of patients with rapidly evolving severe (RES) disease in Sweden. **METHODS:** The original natalizumab model submitted to the UK National Institute for Health and Clinical Excellence (NICE) was adapted to include fingolimod as a comparator treatment and updated with recent epidemiological data from Sweden. The model captures the treatment effect on disability progression and relapse rate. Only direct medical costs were considered and all costs were reported in 2011 SEK. The administration cost of fingolimod was conservatively assumed to be 0 SEK, while the administration cost of natalizumab was 7397 SEK per year. Additional costs included drug acquisition and monitoring costs. Progressive multifocal leukoencephalopathy (PML) and associated disability were incorporated. Quality adjusted life years, life years, and overall cost per patient for both treatment groups were reported and were used to derive incremental cost-effectiveness ratios (ICERs). Probabilistic sensitivity analysis (PSA) was performed to test uncertainty around the model parameters. **RESULTS:** Natalizumab dominated fingolimod (incurs cost savings and additional benefits) in patients with RES over a lifetime horizon. The ICER was 213,926 SEK in the overall patient group, which was below the commonly considered ICER threshold (500,000-700,000 SEK) in health technology assessments in Sweden. PSA showed that over lifetime horizon, the probability of natalizumab being cost-effective at 500,000 SEK threshold was 89% and 62% in RES and overall patient populations, respectively. **CONCLUSIONS:** Natalizumab is a highly cost-effective treatment for both patient groups with RRMS when compared to fingolimod in Sweden.

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A REVIEW OF COST-EFFECTIVENESS STUDIES FOR ANTI-EPILEPTIC DRUGS

Khan N¹, Shah D², Wang Z³, Tongbram V², Verdian L⁴¹Oxford Outcomes Ltd., Morristown, NJ, USA, ²Oxford Outcomes Ltd., an ICON PLC Company,Morristown, NJ, USA, ³Eisai, Inc., Woodcliff Lake, NJ, USA, ⁴Eisai Europe, Hatfield, UK

OBJECTIVES: This study reviews cost-effectiveness (CE) evidence of anti-epileptic drugs (AEDs) in adult patients with epilepsy. **METHODS:** A systematic literature search was conducted in Medline from January 1948 through August 2011 using search terms for seizure, economic analyses and AEDs. Identified studies were screened based on a priori inclusion criteria. Reference lists of the included articles were examined to identify additional studies. Information was extracted on: study design, costs, outcomes, resource and utility data sources, sub-group and sensitivity analyses, and key findings. **RESULTS:** Twenty-four studies were included. Decision-tree modeling was used in 14 studies, followed by Markov modeling in seven studies. Nine studies evaluated the CE of AEDs used as monotherapy, whereas 16 studies evaluated adjunctive use of AEDs. Primary outcomes were seizure freedom in monotherapy studies and >50% reduction in seizure frequency in adjunctive therapy studies. Ten studies assessed drug tolerability. Only two studies used net-

work meta-analysis to compare treatment efficacy across trials. No subgroup analyses were identified. Results varied across studies due to divergent methodology; however, a few themes emerged. For monotherapy in newly diagnosed patients, first-generation AEDs had lower costs but similar outcomes when compared to second-generation AEDs such as lamotrigine. When adjunctive therapies were compared to each other, older AEDs had lower costs but also resulted in lower quality-adjusted life-year gains compared to the newer AEDs such as tiagabine, lacosamide and levetiracetam. **CONCLUSIONS:** There is limited evidence regarding the CE of newer AEDs in refractory patients. Studies in this population that take into account efficacy and tolerability are needed. When head-to-head trials are not available, network meta-analysis should be considered. Additionally, there is no evidence on the CE of AEDs in subgroups, e.g., patients with complex partial seizures and adolescents.

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THE ROLE OF STRUCTURAL SENSITIVITY ANALYSIS IN THE MODELLING OF COST-EFFECTIVENESS (COST-UTILITY) IN PARKINSON'S DISEASE IN THE UNITED STATES AND UNITED KINGDOM

Ratcliffe AE

PHMR Associates, London, UK

OBJECTIVES: To determine the impact of structural sensitivity analysis on conclusions regarding the cost-effectiveness (cost-utility) of pharmaceutical treatments for Parkinson's disease in the USA and the United Kingdom using the EQ-5D, H+Y, Off-time, PDQ-39, and the UPDRS. **METHODS:** We built five separate Markov models (in Microsoft Excel®) for three Parkinson's disease products using published clinical data combined with costs and utilities obtained from published Parkinson's disease cost-utility models to determine the sensitivity of cost-effectiveness conclusions to different structural assumptions. **RESULTS:** We found that that using health states based on the PDQ-39 and UPDRS generated the most favorable cost-effectiveness ratios for each of the three products (across both countries) while using the off-time health state definition led to the least favorable results. This is, perhaps, not surprising since the PDQ-39 and the UPDRS rating scales are Parkinson's disease specific, while the EQ-5D is a generic instrument (PD patients may have particularly poor recall and consequently report inconsistent or implausible HR-QoL values when using generic HRQoL instruments). Finally, the extremely broad nature of the off-time health states led to poorer overall cost-effectiveness results in addition to significantly increasing overall uncertainty in the results -reflected by using cost-effectiveness acceptability curves. **CONCLUSIONS:** We demonstrate through extensive structural sensitivity analysis that whilst conclusions regarding the sensitivity of results to some key parameters (such as health state costs and utilities) can be consistent across different model structures, overall cost-effectiveness can be significantly different (both in terms of expected cost-effectiveness and the corresponding uncertainty) depending on the structural assumptions made. By ignoring structural sensitivity analysis it is possible to erroneously infer that a product may be cost-effective when using a poor choice of structural assumptions; similarly it is possible to erroneously infer that a product may be NOT cost-effective even though structural sensitivity analysis demonstrates this to be unlikely.

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ECONOMIC VALUE OF SLOWING PARKINSON'S DISEASE TO PAYERS AND PATIENTS: MODELING PROGRESSION THROUGH HOEHN AND YAHR STAGES

Johnson S¹, Diener M², Kaltenboeck A², Birnbaum H¹, Grubb E³, Siderowf A⁴¹Analysis Group, Inc., Boston, MA, USA, ²Analysis Group, Inc., New York, NY, USA, ³TevaPharmaceuticals, Kansas City, MO, USA, ⁴University of Pennsylvania, Philadelphia, PA, USA

OBJECTIVES: To estimate the economic benefits of slowing Parkinson's Disease (PD) progression to Medicare, private insurers, and patients. Recent research demonstrated large societal economic gains from slowing PD progression through Hoehn and Yahr (H&Y) stages. Herein, we consider economic benefits captured by Medicare, private insurers, and patients from slowing progression. **METHODS:** A previously-developed model was adapted to evaluate net monetary benefits (NMBs) from a progression rate reduction of 20% to Medicare and patients when PD diagnosis was made at age 60 and to private payers and patients when diagnosis was at age 50. Costs were based on Medicare (N=25,577 patients) and private payer (N=1,151) claims analyses. Income loss associated with PD-related early retirement was estimated using a published model based on disability claims (N=306 employed persons newly diagnosed with PD). Model timeframe was 25 years and outcomes were discounted at 3% annually. Quality-adjusted life-years (QALYs) were based on published health utility data and monetized at \$50,000. Patients were 61% male and assumed to begin 50% in H&Y1 and 50% in H&Y2. **RESULTS:** The diagnosed at age 60 scenario resulted in cost offsets of \$41,207 and QALY gain of 0.50 to Medicare (NMB=\$66,188 if Medicare values QALY gains). From the 60 year-old patient perspective, slower progression leads to saving \$11,800 due to patient out-of-pocket payments, \$17,979 in additional income due to slower PD-related early retirement, and \$24,981 from QALY gains. The diagnosed at age 50 scenario resulted in cost offsets of \$44,081 and QALY gain of 0.52 to the private payer (NMB=\$69,937 if the payer values QALY gains). From the 50-year-old patient perspective, slower progression leads to saving \$12,236 due to patient out-of-pocket payments, \$69,827 from slower early retirement, and \$25,856 due to QALY gains. **CONCLUSIONS:** PD costs are substantial from a Medicare, private insurer, and patient perspective.