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A 16-WEEK, MULTICENTRE, RANDOMIZED, OPEN-LABEL STUDY ASSESSING EFFECTS OF ARIPIPRAZOLE VERSUS OTHER ATYPICALS FOR SCHIZOPHRENIA PATIENTS WITH METABOLIC SYNDROME

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Background: Metabolic syndrome - a significant risk factor for cardiovascular morbidity and mortality - is twice as prevalent among psychiatric patients (21-63%) as general populations (20-24%). Although there is an inherent illness-associated metabolic risk, medications do contribute. Atypicals vary in metabolic risk from high (clozapine, olanzapine), moderate (risperidone, quetiapine) to low (aripiprazole, ziprasidone) (ADA, 2004). Few studies have comprehensively measured cardiovascular risk or directly compared antipsychotics. Limited controlled data show that antipsychotic-induced metabolic abnormalities may be reversible, rationalizing the switch to a lower-risk agent (DeNayer, 2004). Non-HDL-cholesterol encompasses all atherogenic cholesterol and provides a marker of CV risk: an increase of 29ng/dL in diabetics is associated with 50% increased risk (Jiang, 2004). Non-HDL-cholesterol is independently associated with increased risk of non-fatal myocardial infarction and angina.

Aim: This study will provide cross-European data from 13 countries on MS rates in schizophrenia and will assess antipsychotic metabolic profiles and benefits of antipsychotic switching.

Methods: In this ongoing, 16-week, open-label, European multicentre study, 258 schizophrenia patients treated for ≥3 months with olanzapine, risperidone or quetiapine and who have MS will be randomized to switch to aripiprazole (Week 1: 5mg/day; Week 2: 10mg/day; flexible 10-30mg/day after Week 2) or continue with previous antipsychotic. The primary objective is to demonstrate superiority of aripiprazole versus atypicals on mean percentage change of fasting non-HDL-cholesterol from baseline to Week 16.

Conclusion: This study will provide the first direct and comprehensive comparison of metabolic risk with various atypicals in Europe and should impact the future management of schizophrenia.