

# “The Pink Sheet”<sup>®</sup>

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## Prescription Pharmaceuticals & Biotechnology

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### Antipsychotic Drugs Are Medco’s New Personalized Medicine Target

Medco will launch a research project in November that aims to validate a biomarker that may improve the cost effectiveness of atypical antipsychotics. The pharmacy benefit manager announced a research collaboration with development-stage genetic test developer SureGene on Aug. 24.

The research is in line with other Medco programs to use personalized medicine to optimize treatment and reduce costs in cardiovascular disease, where it has focused on warfarin and BristolMyers Squibb/Sanofi Aventis’ *Plavix* (clopidogrel). This is Medco’s first personalized medicine project in the area of mental health.

Medco and SureGene will conduct a prospective clinical trial – called the Relative Effectiveness of Schizophrenia Therapy study – in which DNA samples will be collected from 2,000 subjects drawn from the PBM’s membership. Results are scheduled to be released by the end of 2011.

Medco said the work is expected to be applicable to treatment of both schizophrenia and bipolar disorder with four drugs: Lilly’s *Zyprexa* (olanzapine), risperidone (generics and Johnson and Johnson’s *Risperdal*), AstraZeneca’s *Seroquel* (quetiapine) and Pfizer’s *Geodon* (ziprasidone).

#### Zyprexa For Patients With SULT4A1 Gene

SureGene’s not-yet marketed diagnostic detects a brain-specific enzyme called sulfotransferase family 4A, member 1 (SULT4A1) that interacts with certain neurotransmitters such as dopamine and other catecholamines and neurosteroids. The research will focus on how variation in the gene impacts response to antipsychotics.

For example, if the biomarker is positive for a variant of the gene, the best treatment for the patient would be Zyprexa, SureGene President Richard Marasco said in an interview. If not, the patient is expected to do better on risperidone or another drug. No test for the biomarker is currently on the market.

The research will evaluate the cost effectiveness of using SureGene’s biomarker as a standard part of future clinical care for mental illness. It is expected to support the development of a diagnostic test that would help physicians make better treatment decisions.

Savings could come from reduced hospitalizations, which often result from discontinuation of therapy or poor compliance, as well as a decrease in drug wastage, which can happen as patients are cycled through different therapies before finding one that is appropriate, Medco Personalized Medicine Research and Development Senior Director Bryan Dechairo said.

#### “Optimizing” Dosing For Generics

The effort also reflects Medco’s interest in “optimizing dosing” for generic drugs, Dechairo noted in an interview. Treatment with antipsychotics has primarily relied on the more expensive second-generation atypical drugs despite availability of generics and cost-effectiveness studies challenging their use.

By 2012, three of the four REST study drugs will be available as a generic – risperidone, Zyprexa and Seroquel, with Zyprexa the first to lose its patent, in 2011. Geodon’s patent is set to expire in 2012.

Other atypical antipsychotics on the market include J&J’s injectable risperidone *Risperdal Consta* and Bristol-Myers Squibb’s *Abilify* (aripiprazole) as well as newer entries – Vanda’s *Fanapt* (iloperidone), J&J’s *Invega Sustenna* (long-acting paliperidone), and Merck/Schering-Plough’s *Saphris* (asenapine).

Vanda had been looking at developing a companion pharmacogenetic test focusing on the CNTF gene to understand a differentiation in response for Fanapt. The firm’s interest in identifying the best patient candidates for its drug grew out of pre-approval discussions with FDA on the need for comparative effectiveness data (“The Pink Sheet,” May 11, 2009).

SureGene developed its diagnostic with data from the federally-funded Clinical Antipsychotic Trials of Intervention Effectiveness, or CATIE project. Published in 2005, the research found that the generic perphenazine (Schering’s *Trilafon*) was as effective as the second-generation drugs and less costly, though there were safety advantages to (“The Pink Sheet,” Dec. 11, 2006). SureGene’s Chief Medical Officer Mark Brennan is a National Institutes of Health-approved investigator for the CATIE data.

SureGene President Marasco said the company’s goal is eventually to seek FDA approval to market its diagnostic test commercially. Marasco is a former executive with Abbott, where he spent 25 years in various diagnostic, consumer products, and pharmaceutical management positions.

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