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(For Immediate Release)

i3 DRUG SAFETY TO DELIVER 23 PRESENTATIONS AT ICPE 2009
Diabetes Drugs and Pancreatitis, Safety and Effectiveness of Rotavirus Vaccine, Safety of Duloxetine Therapy

PROVIDENCE, RI, August 13, 2009 -- i3 Drug Safety epidemiologists will present the results of 23 key studies at the 25th anniversary International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE) next week in Providence, RI. Several of these studies drew on information from the large, integrated health care database of i3's parent company Ingenix, an industry leader in health information, technology and consulting.

Diabetes Drugs and Acute Pancreatitis

Several of the i3 Drug Safety presentations focus on diabetes, acute pancreatitis (AP), and the drug exenatide, which has been the subject of spontaneous reports of AP. Because AP reports are rare, studies of health insurance claims data provide an ideal opportunity to reach the population levels needed to evaluate an association between certain diabetes drugs and AP. In both a custom study and one using i3Aperio[®], i3's online tool to identify signals that could indicate a drug's potential safety issues at near-real time, Dore, Seeger, et al, conducted a series of database studies incorporating more than 260,000 patients taking exenatide or other types of antihyperglycemic drugs. The research suggests no increased risk of AP with current use of exenatide compared to other types of antihyperglycemic drugs.

Oral Presentation: Positive Predictive Value (PPV) of Commercial Health Insurance Claims Data for Identifying Acute Pancreatitis (AP) in Patients with Diabetes Mellitus (DM)
Tue, August 18, 11:15-11:30 am

Oral Presentation: Incidence of Acute Pancreatitis in Exenatide Initiators Compared to Other Antidiabetic Drug Initiators: A Retrospective Cohort Study
Wed, August 19, 9:15-9:30 am

Poster Presentation: Active Safety Surveillance of the Risk of Acute Pancreatitis (AP) Associated with Exenatide or Sitagliptin Compared to Metformin or Glyburide
Mon, August 17, 8:00 am-6:00 pm

Rotavirus Vaccine

A decade ago, a rotavirus vaccine was pulled from the market after reports of associated intestinal intussusception (IS) in some of the children; this is a rare and potentially lethal condition in which a section of the intestine prolapses, cutting off blood supply. Rotavirus infection is the leading cause of severe diarrhea and vomiting (gastroenteritis) in children under two and kills around 600,000 children each year, mostly in developing countries. Loughlin, et al, conducted two studies of a new pentavalent rotavirus vaccine (RV5). The first, a two-year, post-market surveillance study, compared the health outcomes of more than 80,000 infants who received RV5 in combination with diphtheria-tetanus-acellular pertussis (DTaP) vaccine to more than 60,000 of those who only received DTaP to evaluate safety. They found no increased risk of intussusception, Kawasaki Disease, or other health outcomes associated with receipt of RV5. The second study of dosing

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adherence found similar rates between the two cohorts. In a third study, Wang, et al, showed that the RV5 vaccine is highly effective against rotavirus, as reflected by incidence of gastroenteritis. It was associated with a 66 percent decrease in all-cause gastroenteritis-related hospitalization and emergency department visit days and a 74 percent reduction in cost.

Oral Presentation: A Post-Marketing Surveillance Program for Pentavalent Rotavirus Vaccine
Mon, August 17
2:45-3:00pm

Oral Presentation: Effectiveness of the Pentavalent Rotavirus Vaccine in Preventing gastroenteritis in the United States: A Claims-Based Analysis
Mon, August 17, 2:15-2:30 pm

Poster Presentation: Adherence to the Pentavalent Rotavirus Vaccine Dosing Schedule in the U.S.: 2006-2007
Wed, August 19, 8:00 am-1:45 pm

Duloxetine

Patients in clinical trials for duloxetine, a serotonin-norepinephrine reuptake inhibitor (SNRI), had small increases in blood pressure and spontaneous cardiovascular events have been observed. Seeger, et al, conducted a large database study of adults with depression taking duloxetine vs. those taking another SNRI, selective serotonin reuptake inhibitors (SSRIs), or tricyclic antidepressants, as well as untreated depressed patients and people without depression, to assess the risk of cardiovascular events. They found no difference between patients taking duloxetine and any of the other depression patients—treated or untreated. However, those patients without depression had a lower incidence of cardiovascular events, suggesting that depression and associated morbidities may affect the risk more than specific antidepressant therapy.

Poster Presentation: Cardiovascular Events in Duloxetine Users Compared to Other Depressed and Non-Depressed Subjects
Mon, August 17, 8:00 am-6:00 pm

About i3

i3, a global Ingenix company, provides integrated scientific strategies and solutions throughout the pharmaceutical product lifecycle. It is composed of i3 Research, a therapeutically specialized contract research organization; i3 Drug Safety, engaged in pharmacovigilance and epidemiology; i3 Pharma Informatics, a data, science and technology provider of market analytics; i3 Statprobe, a leader in comprehensive data services; i3 Pharma Resourcing, a world-class staffing partner; and i3 Innovus, delivering the science and solutions to achieve marketplace success. i3 helps companies gain sharper insights that lead to better patient care. For more information, visit www.i3global.com.

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