

# CAREMARK TrendsRx<sup>®</sup> Alert

What's new...What's next...What to do now

August 2006

**PRE-  
DRUG  
APPROVAL**

## Galvus<sup>®</sup> (vildagliptin) and Januvia<sup>™</sup> (sitagliptin)

Galvus (vildagliptin, Novartis Pharmaceuticals Corporation) and Januvia (sitagliptin, Merck & Co., Inc.) are pending approval by the US Food and Drug Administration (FDA) for the treatment of type 2 diabetes.<sup>1-3</sup>

**Mechanism of Action:**

- Oral dipeptidyl peptidase 4 (DPP-4) inhibitors<sup>1-3</sup>
- Similar mechanism of action to the injectable incretin mimetic, Byetta<sup>®</sup> (exenatide, Amylin Pharmaceuticals, Inc.)<sup>2-4</sup>

**Adverse Effects:**

- Not associated with weight gain<sup>2,3,5</sup>
- Overall incidence of adverse effects, including low blood glucose, was similar to placebo<sup>2,3</sup>

**Approval:**

- Galvus: Late November 2006<sup>6</sup>

**Launch:**

- Galvus and Januvia: Fourth Quarter 2006<sup>6</sup>

**Comments:**

- If approved, Galvus and/or Januvia will be the first in a new class of oral medications for type 2 diabetes.<sup>2,3</sup>
- Galvus and Januvia are once-daily products that have been studied for use alone or in combination with other anti-diabetes medications.<sup>2,7</sup>
- A combination product containing Januvia and metformin, currently known as MK-0431A (Merck & Co., Inc.), is also pending FDA approval for the treatment of type 2 diabetes.<sup>8</sup> Approval is anticipated in March of 2007.<sup>8</sup>

### BACKGROUND

- According to a 2005 estimate from the Centers for Disease Control and Prevention, 20.8 million people in the United States, or 7% of the population, have diabetes.<sup>9</sup>
- About 90% to 95% of people with diabetes have type 2 diabetes.<sup>9</sup>
- The estimated annual total economic cost of diabetes in 2002 was \$132 billion, or more than \$1 of every \$10 spent on healthcare in the United States.<sup>9,10</sup>
- Diabetes was the sixth leading cause of death in the United States in 2002.<sup>9</sup>
- Improved blood glucose control can reduce the risk of certain diabetes complications, including eye, kidney, and nerve disease.<sup>9</sup>

### ECONOMIC IMPACT

- Caremark estimates Galvus will increase pharmacy budgets by approximately \$0.04 to \$0.06 Per Member Per Month (\$0.51 to \$0.67 Per Member Per Year) during its first year on the market.<sup>11</sup>
- Januvia is estimated to increase pharmacy budgets by approximately \$0.06 to \$0.08 Per Member Per Month (\$0.70 to \$0.90 Per Member Per Year) during its first year on the market.<sup>11</sup>
- These estimates assume that Galvus and Januvia will compete as second-line oral therapy for patients with type 2 diabetes.<sup>12</sup> Galvus and Januvia are expected to have comparable pricing and length of therapy.<sup>12</sup>

## CAREMARK RESPONSE

- Caremark recognizes the unique needs of plan participants with diabetes.
- Plan participants requiring Galvus or Januvia may be good candidates for the CarePatterns® Health Management Program for Diabetes. This disease management program helps plan participants with diabetes better manage their condition, including reinforcing the importance of medication compliance, leading to overall decreased healthcare costs and improved outcomes.
- Upon FDA approval, Galvus and Januvia will be considered for inclusion into selected URPlus diabetes interventions. URPlus is a retrospective utilization management program that uses pharmacy and medical claims data to assist with prescriber adherence to national clinical guidelines.
- Caremark will continue to monitor the development of Galvus and Januvia to determine if other clinical programs are needed.

## CAREMARK CONTACT

For more information call your Caremark account representative.

*Please Note: This document provides a brief overview of the subject. This review is provided as a reference only, and is based in part on information derived from third parties.*

### References

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