

**ONGLYZA™ (SAXAGLIPTIN), A NEW TREATMENT FOR TYPE 2 DIABETES  
MELLITUS IN ADULTS, NOW AVAILABLE IN U.S. PHARMACIES**

PRINCETON, NJ, and LONDON, August 14, 2009 – [Bristol-Myers Squibb Company](#) (NYSE: BMY) and [AstraZeneca](#) (NYSE: AZN) today announced that [ONGLYZA™](#) (saxagliptin), a dipeptidyl peptidase-4 (DPP4) inhibitor, approved by the U.S. Food and Drug Administration (FDA) on July 31, 2009, is now available, by prescription, in pharmacies across the United States. Bristol-Myers Squibb and AstraZeneca began shipping ONGLYZA to wholesalers the next business day following the FDA approval.

ONGLYZA is indicated as an adjunct to diet and exercise to improve blood sugar (glycemic) control in adults for the treatment of type 2 diabetes mellitus. ONGLYZA once daily can be used in combination with commonly prescribed oral anti-diabetic medications – metformin, sulfonylureas or thiazolidinediones (TZD) – or as a monotherapy to significantly reduce glycosylated hemoglobin (A1C) levels. ONGLYZA should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis (high levels of certain acids, known as ketones, in the blood or urine). ONGLYZA has not been studied in combination with insulin.

**IMPORTANT INFORMATION ABOUT ONGLYZA**

**Indication and Important Limitations of Use**

ONGLYZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

ONGLYZA should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

ONGLYZA has not been studied in combination with insulin.

## Important Safety Information

- **Use With Medications Known to Cause Hypoglycemia:** Insulin secretagogues, such as sulfonylureas, cause hypoglycemia. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with ONGLYZA™ (saxagliptin).
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ONGLYZA or any other antidiabetic drug.

**Most common adverse reactions** (regardless of investigator assessment of causality) reported in  $\geq 5$  percent of patients treated with ONGLYZA and more commonly than in patients treated with control were upper respiratory tract infection (7.7 percent, 7.6 percent), headache (7.5 percent, 5.2 percent), nasopharyngitis (6.9 percent, 4.0 percent) and urinary tract infection (6.8 percent, 6.1 percent). When used as add-on combination therapy with a thiazolidinedione, the incidence of peripheral edema for ONGLYZA 2.5 mg, 5 mg, and placebo was 3.1 percent, 8.1 percent and 4.3 percent, respectively.

**Drug Interactions:** Because ketoconazole, a strong CYP3A4/5 inhibitor, increased saxagliptin exposure, the dose of ONGLYZA should be limited to 2.5 mg when coadministered with a strong CYP3A4/5 inhibitor (e.g., atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin).

**Patients with Renal Impairment:** The dose of ONGLYZA is 2.5 mg once daily for patients with moderate or severe renal impairment, or with end-stage renal disease requiring hemodialysis (creatinine clearance  $\leq 50$  mL/min). ONGLYZA should be administered following hemodialysis. ONGLYZA has not been studied in patients undergoing peritoneal dialysis. Assessment of renal function is recommended prior to initiation of ONGLYZA and periodically thereafter.

**Pregnant and Nursing Women:** There are no adequate and well-controlled studies in pregnant women. ONGLYZA, like other antidiabetic medications, should be used during pregnancy only if clearly needed. It is not known whether saxagliptin is secreted in human milk. Because many

drugs are secreted in human milk, caution should be exercised when ONGLYZA™ (saxagliptin) is administered to a nursing woman.

**Pediatric Patients:** Safety and effectiveness of ONGLYZA in pediatric patients have not been established.

Please see accompanying US Full Prescribing Information or visit [www.bms.com](http://www.bms.com).

### **Bristol-Myers Squibb and AstraZeneca Collaboration**

Bristol-Myers Squibb and AstraZeneca entered into a collaboration in January 2007 to enable the companies to research, develop and commercialize select investigational drugs for type 2 diabetes. The Bristol-Myers Squibb/AstraZeneca Diabetes collaboration is dedicated to global patient care, improving patient outcomes and creating a new vision for the treatment of type 2 diabetes.

### **About Bristol-Myers Squibb**

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information, visit [www.bms.com](http://www.bms.com).

### **About AstraZeneca**

AstraZeneca is a major international healthcare business engaged in the research, development, manufacturing and marketing of meaningful prescription medicines and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with global healthcare sales of \$31.6 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infectious disease medicines. In the United States, AstraZeneca is a \$13.5 billion dollar healthcare business. For more information about AstraZeneca, please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

### **Bristol-Myers Squibb Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 relating to the development and commercialization of certain compounds. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any

of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that ONGLYZA™ (saxagliptin) will be commercially successful. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2008, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

### **AstraZeneca Forward-Looking Statement**

The statements contained herein include forward-looking statements. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of the preparation of this press release and the Company undertakes no obligation to update these forward-looking statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things, those risk factors identified in the Company's Annual Report/Form 20-F for 2008. Nothing contained herein should be construed as a profit forecast.

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ONGLYZA is a trademark of the Bristol-Myers Squibb Company.

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