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FDA Advisory Committee Recommends Approval of Canagliflozin for Treatment of Adults with Type 2 Diabetes

RARITAN, N.J., Jan. 10, 2013 /PRNewswire/ -- Janssen Research & Development, LLC (Janssen) announced today that the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted 10-5 to recommend approval for canagliflozin, proposed trade name INVOKANA™, to treat type 2 diabetes in adult patients based on the efficacy and safety results from its comprehensive clinical development program.

Canagliflozin is an investigational, oral, once-daily medication for the treatment of adult patients with type 2 diabetes. If approved by the FDA later this year, it would be the first in this new class of diabetes therapies available in the U.S. The kidneys of people with type 2 diabetes reabsorb greater amounts of glucose back into the body compared to people who do not have diabetes, which may contribute to elevated glucose levels. Canagliflozin, a selective sodium glucose co-transporter 2 (SGLT2) inhibitor, blocks the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in people with diabetes who have elevated blood glucose levels.

"We are pleased with the positive recommendation from the committee and look forward to working with the FDA to bring this important new therapy to patients in the U.S. to help them manage their type 2 diabetes," said Peter Stein, M.D., Head, Metabolism Development, Diabetes Disease Area Leader, Janssen. "Today's outcome represents an important step toward achieving that goal."

Data presented at today's advisory committee meeting included results from the comprehensive global Phase 3 clinical program, which enrolled 10,285 patients in nine studies; it is the largest late-stage development program for an investigational pharmacologic product for the treatment of type 2 diabetes submitted to health authorities to date. Canagliflozin was evaluated at 100 mg and 300 mg once-daily doses in placebo- and active comparator-controlled studies, as well as three large studies in special populations: older patients, patients with moderate renal impairment, and patients who had or were at risk for cardiovascular disease. Results showed that in addition to the improvements in glycemic control, both doses of canagliflozin were associated with weight loss and reductions in blood pressure across clinical studies.

Canagliflozin was generally well tolerated. It has specific safety and tolerability issues that were well characterized in this development program (such as the genital mycotic infections, urinary tract infections) and can be well managed by the physician, and for some of these issues by the patient.

Janssen presented data from Phase 3 studies at the American Diabetes Association ([ADA](#)) in Philadelphia in June, at the European Association for the Study of Diabetes ([EASD](#)) in Berlin in October, and at the World Congress on Controversies to Consensus in Diabetes, Obesity, and Hypertension ([CODHy](#)) in Barcelona in November.

The FDA will consider the advisory committee recommendation in its review of the New Drug Application (NDA) for canagliflozin that was [submitted by Janssen](#) on May 31, 2012, though the FDA is not bound to follow it.

Janssen and its affiliates have rights to canagliflozin through a license agreement with Mitsubishi Tanabe Pharma Corporation. Janssen Pharmaceuticals, Inc. and its affiliates have marketing rights in North America, South America, Europe, the Middle East, Africa, Australia, New Zealand, and parts of Asia.

About Type 2 Diabetes

The ADA estimates that 26 million Americans have type 2 diabetes. Type 2 diabetes is a chronic condition that affects the body's ability to metabolize sugar, or glucose, and is characterized by the inability of pancreatic beta cell function to keep up with the body's demand for insulin. In most people with type 2 diabetes, obesity causes resistance of the body to the action of insulin, and if the pancreatic beta cell cannot produce enough insulin, hyperglycemia and type 2 diabetes ensue.

If left uncontrolled, type 2 diabetes can lead to serious long-term microvascular complications such as nerve disease leading to amputation, retinopathy resulting in blindness and nephropathy causing end-stage renal disease. Improved glycemic control has been demonstrated to reduce the onset and progression of these complications. About half of patients with type 2 diabetes do not achieve levels of glucose control recommended by their doctor.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development, LLC and Janssen Pharmaceuticals, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit <http://www.janssenrnd.com> for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of healthcare products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments).

Media contacts:

Christina Chan
Phone: (908) 927-5769
cchan20@its.jnj.com

Bill Foster
Phone: (908) 704-4404
wfooster@its.jnj.com

Investor contacts:

Stan Panasewicz
Phone: (732) 524-2524

Louise Mehrotra
Phone: (732) 524-6491

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