



News Release Media Contacts

Europe Middle-East & Africa

Brigitte Byl
Phone: +3214607172
bbyl@its.jnj.com

Global

Christina Chan
Phone: + 1 (908) 927-5769
Mobile: +1 (908) 635-2406
cchan20@its.jnj.com

Investor contacts:

Stan Panasewicz
Phone: + 1 (732) 524-2524

Louise Mehrotra
Phone: + 1 (732) 524-6491

New and Long-Term Use Results for canagliflozin to be presented at European Association for the Study of Diabetes Annual Meeting

Latest results from 52- and 102-week analyses from the large clinical development programme for canagliflozin add to the safety and efficacy profile of the SGLT2 inhibitor

Beerse, Belgium, 18th September, 2013 – Janssen-Cilag International NV (Janssen) announced today that 12 presentations on canagliflozin will be made at the upcoming annual meeting of the European Association for the Study of Diabetes (EASD), from September 24-27 in Barcelona, Spain.

The accepted abstracts include the first presentation of 52-week data results from the Phase 3 trial DIA3002 evaluating canagliflozin compared to placebo in adult patients with type 2 diabetes who are on a background therapy with metformin and a sulfonylurea.

“We look forward to sharing the latest data for canagliflozin with the scientific community at EASD,” said Norman Rosenthal, MD, FACE, FACP, Compound Development Team Leader for canagliflozin at Janssen Research & Development, LLC. “We believe the new analyses from our robust Phase 3 clinical programme will provide a deeper understanding of canagliflozin and the approach of SGLT2 inhibition.”

In the European Union, canagliflozin is currently under consideration with the European Medicines Agency (EMA). In the US, canagliflozin was [approved](#) with the brand name INVOKANA™ in March 2013 by the U.S. Food and Drug Administration for the treatment of adult patients with type 2 diabetes, and is the first in a new class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors available in the United States.

In total, 12 abstracts with results from the canagliflozin Phase 3 programme will be presented at the 2013 annual meeting of the EASD; they are listed below for reference. All times listed as Central European Summer Time (CEST). The EASD program is available via the [EASD Virtual Meeting](#). Please note that all abstracts accepted for presentation at EASD are subject to the organisers' embargo policies.

- Poster session #073, "SGLT-2 clinical trials", on Tuesday, September 24th from 12:30 to 1:30 p.m.
 - Canagliflozin added on to dipeptidyl peptidase-4 inhibitors or glucagon-like peptide-1 agonists with or without other antihyperglycaemic agents in type 2 diabetes mellitus (results from DIA3008, [abstract #933](#)([Abstract #933](#)))
 - Efficacy and safety of canagliflozin in subjects with type 2 diabetes mellitus inadequately controlled with metformin plus sulphonylurea over 52 weeks (results from DIA3002, [abstract #934](#))
 - Efficacy and safety of canagliflozin monotherapy in subjects with type 2 diabetes mellitus inadequately controlled with diet and exercise over 52 weeks (results from DIA3005, [abstract #935](#))

- Poster session #079, "Novel approaches to treat type 1 and type 2 diabetes", on Tuesday, September 24th from 12:30 to 1:30 p.m.
 - Effects of one-year treatment with canagliflozin or sitagliptin on glycaemic control and beta cell function measures in subjects with type 2 diabetes on metformin + sulphonylurea (results from DIA3015, [abstract #993](#))

- Poster session #074, "SGLT-2 inhibitors: influence on cardiovascular risk factors", on Tuesday, September 24th from 1:45 to 2:45 p.m.
 - Effects of canagliflozin on blood pressure and adverse events related to osmotic diuresis and reduced intravascular volume in subjects with type 2 diabetes mellitus (pooled analysis of Phase 3 studies, [abstract #945](#))
 - Canagliflozin lowers HbA1c and blood pressure through weight loss-independent and weight loss-associated mechanisms (pooled analysis of Phase 3 studies, [abstract #946](#))

- Poster session #075, "SGLT-2 inhibitors: side effects, special populations", on Wednesday, September 25th from 12:30 to 1:30 p.m.
 - Urinary tract infection with canagliflozin in subjects with type 2 diabetes mellitus (pooled analysis of Phase 3 studies, [abstract #949](#))
 - Genital mycotic infections with canagliflozin in subjects with type 2 diabetes mellitus (pooled analysis of Phase 3 studies, [abstract #950](#))
 - Efficacy and safety of canagliflozin in subjects with type 2 diabetes mellitus and chronic kidney disease over 52 weeks (results from DIA3004, [abstract #951](#))
 - Canagliflozin is effective and generally well tolerated in subjects with type 2 diabetes mellitus and Stage 3 chronic kidney disease (pooled analysis of Phase 3 studies, [abstract #953](#))
 - Efficacy and safety of canagliflozin in older subjects with type 2 diabetes mellitus (pooled analysis of Phase 3 studies, [abstract #955](#)([Abstract #955](#)))

- Oral presentation session #31, "Glucose down the drain", on Thursday, September 26th from 3:00 to 4:30 p.m.
 - Canagliflozin demonstrates durable glycaemic improvements over 104 weeks compared with glimepiride in subjects with type 2 diabetes mellitus on metformin (results from DIA3009, [abstract #182](#)([Abstract #182](#)))

Results from Phase 3 studies for canagliflozin have been published^{1,2,3} and presented at the American Diabetes Association (ADA) Annual Scientific Sessions in [June 2012](#) and [June 2013](#), at the European Association for the Study of Diabetes (EASD) Annual Meeting in [October 2012](#), and at the World Congress on Controversies to Consensus in Diabetes, Obesity, and Hypertension (CODHy) in [November 2012](#).

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

About Janssen

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases.

Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world.

More information can be found at www.janssen-emea.com

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² Yale JF, Bakris G, Cariou B, Yue D, David-Neto E, Xi L, Figueroa K, Wajs E, Usiskin K, Meininger G. Efficacy and safety of canagliflozin in subjects with type 2 diabetes and chronic kidney disease. *Diabetes Obes Metab*. 2013 May;15(5):463-73.

³ Stenlöf K, Cefalu WT, Kim KA, Alba M, Usiskin K, Tong C, Canovatchel W, Meininger G. Efficacy and safety of canagliflozin monotherapy in subjects with type 2 diabetes mellitus inadequately controlled with diet and exercise. *Diabetes Obes Metab*. 2013 Apr;15(4):372-82.