ASTRAZENECA PLC
Form 6-K
May 13, 2014

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of May 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

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ASTRAZENECA ANNOUNCES POSITIVE RESULTS FROM PHASE III STUDY OF SAXAGLIPTIN/DAPAGLIFLOZIN COMBINATION IN PATIENTS WITH TYPE 2 DIABETES INADEQUATELY CONTROLLED ON METFORMIN AND OUTLINES FUTURE DEVELOPMENT PLANS

FOR THE ORAL ANTIDIABETIC FRANCHISE

Study showed patients inadequately controlled on metformin achieved statistically significant reduction of HbA1c with the combination of saxagliptin and dapagliflozin versus either agent alone

Overall rates of adverse events similar between the three treatment groups, and most were reported as mild or moderate in intensity. Improvements in glycaemic control achieved without increased risk of hypoglycaemia with more patients reaching goal HbA1c levels of less than 7% and were associated with body weight reduction

AstraZeneca will commence a Phase III trial for dapagliflozin in patients with Type 1 diabetes in 2014

AstraZeneca today announced results from a Phase III study evaluating the investigational combination of saxagliptin/dapagliflozin as a dual add-on therapy in adult patients with type 2 diabetes who were inadequately controlled on metformin.

Results from the combination study found that patients treated with saxagliptin/dapagliflozin plus metformin achieved significantly greater reductions in HbA1c versus either agent alone plus metformin at 24 weeks, with an adjusted mean change from baseline HbA1c of -1.47% in the saxagliptin/dapagliflozin combination group compared to -0.88% in the saxagliptin group and -1.20% in the dapagliflozin group. More patients in the saxagliptin/dapagliflozin combination group (41%) achieved goal HbA1c levels of less than 7% compared to patients in the saxagliptin (18%) and dapagliflozin (22%) groups.[i]

The saxagliptin/dapagliflozin combination group achieved a significantly greater adjusted mean reduction from baseline in two-hour postprandial glucose (PPG) versus the saxagliptin group, but not the dapagliflozin group. The adjusted mean reduction in fasting plasma glucose (FPG) was greater in the saxagliptin/dapagliflozin combination group (-38 mg/dL) than the saxagliptin group (-14 mg/dL), but similar to the dapagliflozin group (-32 mg/dL). In this study, overall rates of adverse events, including hypoglycaemia, were similar between the three treatment groups, and most were reported as mild or moderate in intensity.

"Diabetes is a progressive disease in which nearly half of patients do not achieve their HbA1c goals. Despite the standard sequential use of existing therapies, there is a need for new and earlier therapeutic approaches that provide more robust HbA1c lowering," said lead investigator Julio Rosenstock, MD, director of the Dallas Diabetes and Endocrine Center at Medical City and clinical professor of medicine at the University of Texas Southwestern Medical School, Dallas, Texas. "What we've observed in this trial is when the two independent mechanisms of action of saxagliptin and dapagliflozin are used in combination, significant reductions in HbA1c associated with weight loss are achieved in patients not adequately treated with metformin alone, and more patients reached the HbA1c target goal without increased risk of hypoglycaemcia while maintaining a similar safety profile to the individual monotherapies."

"The results for the combination of saxagliptin and dapagliflozin demonstrate our continued commitment to meeting the needs of patients with type 2 diabetes by working to understand how these two medicines with independent mechanisms of action may be used together to help more patients achieve their treatment goals," said Briggs Morrison, Executive Vice President, Global Medicines Development & Chief Medical Officer, AstraZeneca.

This 24-week, Phase III, multi-center, randomised, double-blind, active-controlled, parallel-group trial was designed to evaluate the efficacy and safety of the combination of saxagliptin/dapagliflozin as dual add-on therapy in adult patients with type 2 diabetes with inadequate glycaemic control on metformin. The primary endpoint was mean change in HbA1c from baseline to week 24. Secondary endpoints included mean change from baseline in two-hour PPG during a liquid meal test, FPG, body weight at week 24 in the saxagliptin/dapagliflozin combination group versus the saxagliptin group, and the proportion of patients who achieved glycaemic response (defined as HbA1c < 7%).1

The study included 534 adult patients with type 2 diabetes (aged ≥ 18 years) with inadequate glycaemic control (HbA1c ≥ 8% and ≤ 12%) who were receiving metformin extended-release (≥ 1,500 mg per day). Patients were randomised 1:1:1 to receive the combination of saxagliptin 5 mg and dapagliflozin 10 mg added to metformin, saxagliptin and metformin added to placebo, or dapagliflozin and metformin added to placebo, for 24 weeks.1

Future Development of AstraZeneca Oral Anti-Diabetic Franchise
Type 1 diabetes patients are dependent on lifelong insulin injections which present a constant risk for hypoglycaemic events and long term weight gain.
AstraZeneca will commence a Phase III trial for dapagliflozin in patients with Type 1 diabetes in 2014.

About DPP4 inhibitors and SGLT2 inhibitors
Saxagliptin (marketed as Onglyza®) belongs to the class of medicines called DPP-4 inhibitors, which work by increasing the activity of the incretin hormones, increasing the release of insulin when glucose levels are elevated and reducing the levels of sugar produced by the liver (glucagon).[ii] Dapagliflozin (marketed as Farxiga™ in the U.S. and Forxiga® outside the U.S.) is part of a newer class of medicines called sodium-glucose cotransporter 2 (SGLT2) inhibitors, which remove glucose via the kidneys.

About Type 2 Diabetes
Diabetes is estimated to affect 25.8 million people in the U.S. and more than 382 million people worldwide. The prevalence of diabetes is projected to reach more than 592 million people worldwide by 2035.[iii] Type 2 diabetes accounts for approximately 90-95 percent of all cases of diagnosed diabetes in adults.[iv] Type 2 diabetes is a chronic disease[v] characterised by pathophysiologic defects leading to elevated glucose levels.[vi] Over time, this sustained hyperglycaemia contributes to further progression of the disease.[vii] Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen.[viii]

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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13 May 2014

ENDS

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 13 May 2014

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary