

### **AstraZeneca Pharma India Limited launches FORXIGA® - a breakthrough treatment of Type 2 diabetes in India**

**Thursday, June 11, 2015**

AstraZeneca Pharma India Limited (AstraZeneca India), a leading biopharmaceutical company, today announced the launch of FORXIGA® (dapaglifozin), a breakthrough treatment for Type 2 diabetes mellitus.

FORXIGA® belongs to a new class of Type 2 diabetes mellitus medication—a highly selective inhibitor of sodium-glucose cotransporter 2 (SGLT2). It has an unique insulin independent mode of action that helps remove excess glucose from the body via urine which is associated with reductions in glycated haemoglobin (HbA1c), weight and systolic blood pressure. Globally, FORXIGA® is the first medicine in the new SGLT2 inhibitor class to gain regulatory approval for the treatment of Type 2 diabetes mellitus.

FORXIGA® tablets are indicated as a once-daily oral medication to improve glycaemic control in adult patients with Type 2 diabetes mellitus. FORXIGA® is indicated to be used as an adjunct to diet and exercise in combination with other glucose-lowering medicinal products, including insulin, or as a monotherapy in metformin-intolerant patients.

Diabetes mellitus is a disease of epidemic scale in India, with more than 63 million affected people. With many diabetic patients remaining uncontrolled in their glucose lowering regimen, and Type 2 diabetes mellitus being increasingly associated with overweight/ obesity, a term coined as 'Diabesity' by researchers, FORXIGA® offers a new treatment approach for patients and physicians that helps in improving glycaemic control with added benefits of weight loss and blood pressure reduction

FORXIGA® is currently approved in more than 40 countries. In India, it has been approved by the Drugs Controller General of India on 25th February, 2015 supported by a broad clinical development programme comprising 11,801 patients in various clinical studies evaluating the safety and efficacy of FORXIGA®.

AstraZeneca India has an innovative non – insulin anti-diabetic product portfolio offering physicians treatment options across the spectrum that meets the individual needs of diabetic patients. AstraZeneca is the first to offer products in three novel and fast growing classes of diabetes treatments: Dipeptidyl Peptidase-4 (DPP-4) inhibitors, SGLT-2 inhibitor and glucagon-like peptide 1 (GLP-1) agonists. AstraZeneca India markets two patented molecules under the brands- ONGLYZA® (Saxagliptin) and KOMBIGLYZE XR™ in the DPP4i segment, BYETTA® in the GLP1 analogues treatment segment and now FORXIGA® in the SGLT2i segment.

## News Release

**Mr. Sanjay Murdeshwar, Managing Director, AstraZeneca Pharma India Limited** said, "FORXIGA® represents a significant advancement in the treatment of Type 2 diabetes mellitus with global safety and efficacy data of 4 years. It is an important addition to our innovative anti-diabetic portfolio; strengthening our commitment to transform patient care in diabetes by offering an additional treatment option for over 63 million diabetic patients in India."

**Dr. Bhavesh Kotak, Vice President, Medical and Regulatory Affairs, AstraZeneca Pharma India Limited** explained "Reaching treatment goals of diabetic patients continues to be a challenge in spite of multiple therapeutic options of oral and injectable anti diabetic agents. FORXIGA® works by blocking reabsorption of glucose in the kidneys. Excess glucose gets excreted via urine helping patients achieve glycaemic control, a major treatment goal"

FORXIGA® is available in the markets from May 2015.

### NOTES TO EDITORS

#### **About Forxiga® (Dapagliflozin)**

FORXIGA® tablets are approved as a once-daily oral medication in adult patients with Type 2 diabetes mellitus to improve glycaemic control:

- As a monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance; or
- In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

FORXIGA® is not indicated as a weight loss product or for the management of obesity or high blood pressure, and has only been studied for the treatment of Type 2 diabetes.

#### **About SGLT2 Inhibition**

The kidney plays a contributing role in maintaining normal glucose balance, in part by filtering and subsequently reabsorbing glucose back into circulation. SGLT2, a sodium-glucose cotransporter found predominantly in the kidney, is responsible for the majority of glucose reabsorption. Selective inhibition of SGLT2 reduces the reabsorption of glucose and enables its removal via urine, which is associated with reductions in HbA1c, weight and blood pressure.

#### **About Type 2 diabetes mellitus**

Diabetes mellitus is estimated to affect about 63 million people in India and more than 382 million people worldwide. The prevalence of diabetes is projected to reach more than 592 million people worldwide by 2035. Type 2 diabetes mellitus is a chronic disease characterised by pathophysiologic defects leading to elevated glucose levels. Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen. It is estimated that more than half of people living with Type 2 diabetes mellitus are not achieving recommended HbA1c goals based on guidelines established by professional societies and advocacy organisations for diabetes management.

#### **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](http://www.astrazeneca.com)

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### **About AstraZeneca Pharma India Limited**

In India, AstraZeneca has been successfully growing its presence in important therapeutic areas of Diabetes, Cardiovascular, Infection, Respiratory and Oncology. With a state-of-the-art tablet manufacturing laboratory facility in Bengaluru, AstraZeneca is driving quality and innovation in India. AstraZeneca India employs more than 1500 people in sales, marketing and manufacturing and is committed to having a significant presence in the country. For more information please visit: [www.astrazeneca.com/india](http://www.astrazeneca.com/india)

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