October 20, 2023

BSE Limited **Code: 532321**
1st Floor,
P J Towers,
Dalal Street,
Mumbai-400001

National Stock Exchange of India Limited **Code: Zyduslife**
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated October 20, 2023 titled **"Zydus receives USFDA approval for ZITUVIO™ to treat adult patients with type 2 diabetes mellitus"**.

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Thanking you,

Yours faithfully,
For, **ZYDUS LIFESCIENCES LIMITED**

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2023.10.20 17:53:16 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

Zydus receives USFDA approval for ZITUVIO™ to treat adult patients with type 2 diabetes mellitus

The company received final approval from the USFDA for its New Drug Application (NDA) for ZITUVIOTM (Sitagliptin) tablets, 25 mg, 50 mg, and 100 mg.

October 20th, 2023, Ahmedabad, India

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as "Zydus") today announced that the U.S. Food and Drug Administration (FDA) approved its New Drug Application (NDA) for ZITUVIO™ (Sitagliptin) tablets, 25 mg, 50 mg, and 100 mg.

ZITUVIO™ contains active ingredient Sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

The approval of ZITUVIO™ is based on research, development, regulatory and manufacturing work performed by Zydus teams. ZITUVIO™ has undergone quality testing for Nitrosamines and potential genotoxic impurities as per current USFDA standards. ZITUVIO™ is compliant with current USFDA standards of Nitrosamines in Sitagliptin containing products.

"The ZITUVIO™ approval builds on Zydus' long-term commitment to offer healthcare professionals a new affordable treatment option in connection with diabetes management", said Dr. Sharvil Patel, Managing Director of Zydus Lifesciences Limited.

"We are pleased to be able to receive such a milestone approval for Zydus. Through our industry leading capabilities, we pride ourselves in finding innovative ways to bring value to the healthcare systems by providing affordable medicines for our patients. We look forward to bringing additional innovative products in the future that align with our purpose to empower patients to live healthier and more fulfilled lives", said Dr. Punit Patel, CEO of Zydus Pharmaceuticals- Americas.

According to IQVIA™ (MAT Aug-2023), U.S. market for DPP-IV inhibitors and its combinations is US$ 10 bn.

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global life sciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs 25000 people worldwide and is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. For more details visit www.zyduslife.com.

IMPORTANT SAFETY INFORMATION FOR ZITUVIO™ (Sitagliptin)

INDICATIONS AND USAGE

ZITUVIO™ is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use:

- ZITUVIO™ is not recommended in patients with type 1 diabetes mellitus.
- ZITUVIO™ has not been studied in patients with a history of pancreatitis.

DOSAGE AND ADMINISTRATION

The recommended dosage of ZITUVIO™ is 100 mg orally once daily. ZITUVIO™ can be taken with or without food.
Dosage adjustment is recommended for patients with eGFR less than 45 mL/min/1.73 m2.

Dosage Adjustment in Patients with Renal Impairment	
eGFR greater than or equal to 30 mL/min/1.73 m^2 to less than 45 mL/min/1.73 m^2	eGFR less than 30 mL/min/1.73 m^2 (including patients with end stage renal disease [ESRD] on dialysis)
50 mg once daily	25 mg once daily

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DOSAGE FORMS AND STRENGTHS

Tablets: 100 mg, 50 mg, and 25 mg

CONTRAINDICATIONS

History of a serious hypersensitivity reaction to sitagliptin or any of the excipients in ZITUVIO™, such as anaphylaxis or angioedema

WARNINGS AND PRECAUTIONS

- *Pancreatitis:* There have been post marketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. If pancreatitis is suspected, promptly discontinue ZITUVIO™

- *Heart failure:* Heart failure has been observed with two other members of the DPP-4 inhibitor class. Consider risks and benefits of ZITUVIO™ in patients who have known risk factors for heart failure. Monitor patients for signs and symptoms.

- *Acute Renal Failure:* Has been reported post marketing, sometimes requiring dialysis. Assessment of renal function is recommended prior to initiating ZITUVIO™ and periodically thereafter.

- *Hypoglycemia with Concomitant Use with Insulin or Insulin Secretagogues:* Increased risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Lower dose of insulin or insulin secretagogue may be required.

- *Hypersensitivity Reactions:* There have been post marketing reports of serious allergic and hypersensitivity reactions in patients treated with sitagliptin such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. Promptly stop ZITUVIO™, assess for other potential causes, institute appropriate monitoring and treatment.

- *Severe and Disabling Arthralgia:* Has been reported in patients taking DPP-4 inhibitors. Consider as a possible cause for severe joint pain and discontinue drug if appropriate.

- *Bullous Pemphigoid:* There have been post marketing reports requiring hospitalization in patients taking DPP-4 inhibitors. Tell patients to report development of blisters or erosions. If bullous pemphigoid is suspected, discontinue ZITUVIO™.

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