

February 5, 2021

Listing Department

BSE LIMITED

P J Towers, Dalal Street, Fort,
Mumbai – 400 001

Code: **532 321**

Listing Department

NATIONAL STOCK EXCHANGE OF INDIA LIMITED

Exchange Plaza, Bandra Kurla Complex,
Bandra (E),
Mumbai – 400 051

Code: **CADILAHC**

Re.: Press Release

Dear Sir/Madam,

Please find enclosed a copy of press release dated February 5, 2021 titled "Zydus completes large scale enrolment for two Phase III trials of Desidustat."

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, **CADILA HEALTHCARE LIMITED**



DHAVAL N. SONI
COMPANY SECRETARY



Encl.: As above

Zydus completes large scale enrolment for two Phase III trials of Desidustat

Dr. H. K. Choudhary, President, Zydus Research Limited, Gandhinagar, Ahmedabad, India

Ahmedabad, India: Zydus Research Limited, Gandhinagar, Ahmedabad, India, today announced that it has completed the enrolment of patients for two Phase III clinical trials of Desidustat, a novel oral hypoglycaemic agent, in Type 2 Diabetes Mellitus (T2DM).

The first trial is a randomised, double-blind, placebo-controlled, parallel-group study comparing Desidustat with Placebo in T2DM patients. The second trial is a randomised, double-blind, placebo-controlled, parallel-group study comparing Desidustat with Placebo in T2DM patients.

The enrolment of patients for the two Phase III clinical trials of Desidustat is a major milestone in the development program of Desidustat, and we are grateful to all the patients and investigators who have provided to the scientific research in the field of T2DM.

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The enrolment of patients for the two Phase III clinical trials of Desidustat is a major milestone in the development program of Desidustat, and we are grateful to all the patients and investigators who have provided to the scientific research in the field of T2DM. The primary end-point in Phase III DESIDUSTAT randomised study (24 arms) will be the efficacy of Desidustat tablet versus Placebo with objective based on the change of haemoglobin (Hb) levels. The secondary end-points will include number of hypoglycaemic (Hb) episodes, time to achieve target HbA1c, percentage of time spent in target HbA1c range, weight, body mass index (BMI), serum lipids, serum uric acid, serum creatinine (SCr), serum urea, serum electrolytes, serum albumin (ALB), serum total protein (TP), serum total cholesterol (TC), serum triglycerides (TG), serum HDL cholesterol (HDL-C), serum LDL cholesterol (LDL-C), serum VLDL cholesterol (VLDL-C), serum total lipids and lipoproteins.

"The completion of patient enrolment into the DESIDUSTAT and DESIDUSTAT Phase III trials is a major milestone in the development program of Desidustat, and we are grateful to all the patients and investigators who have provided to the scientific research in the field of T2DM. DESIDUSTAT is predicted to show superior efficacy for patients with Chronic Kidney Disease", said Dr. H. K. Choudhary, President, Zydus Research Limited, Gandhinagar, Ahmedabad, India. "The completion of patient enrolment for the two Phase III clinical trials of Desidustat is a major milestone in the development program of Desidustat, and we are grateful to all the patients and investigators who have provided to the scientific research in the field of T2DM. DESIDUSTAT is predicted to show superior efficacy for patients with Chronic Kidney Disease", said Dr. H. K. Choudhary, President, Zydus Research Limited, Gandhinagar, Ahmedabad, India. "The completion of patient enrolment for the two Phase III clinical trials of Desidustat is a major milestone in the development program of Desidustat, and we are grateful to all the patients and investigators who have provided to the scientific research in the field of T2DM. DESIDUSTAT is predicted to show superior efficacy for patients with Chronic Kidney Disease", said Dr. H. K. Choudhary, President, Zydus Research Limited, Gandhinagar, Ahmedabad, India.

For further information please contact:
The Corporate Communications Department

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Desidustat had previously met its primary endpoints in the Phase II clinical studies and showed good safety profile, endogenous production of erythropoietin, downregulation of hepcidin, improved iron mobilization and reduced triglycerides in CKD patients. The Phase I trials were earlier completed in Australia. Zydu has recently reported that Desidustat is Phase IIb RCT

syndrome (ARDS) in COVID-19 patients and also reduced anti-inflammatory markers including CRP and IL-6. [ClinicalTrials.gov Identifier: NCT04468602]. Desidustat is also under clinical trials for Cancer Chemotherapy Induced Anemia (CIA) [ClinicalTrials.gov Identifier: NCT04667533].

Publications on Desidustat (ZYANI):

1. Outcomes of Desidustat Treatment in People with Anemia and Chronic Kidney Disease: A Phase 2 Study. *Am J Nephrol*. 2019;49:470-478.
2. Phase I Clinical Study of ZYANI, A Novel Prolyl-Hydroxylase (PHD) Inhibitor to Evaluate the Safety, Tolerability, and Pharmacokinetics Following Oral Administration in Healthy Volunteers. *Clin Pharmacokinet*. 2018 Jan; 57(1):87-102
3. Influence of acute and chronic kidney failure in rats on the disposition and pharmacokinetics of ZYANI, a novel prolyl hydroxylase inhibitor, for the treatment of chronic kidney disease-related anemia. *Int J Pharm*. 2019; 569:1-10