

THRU ONLINE FILING

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BSE Ltd.
Phiroze Jeejeebhoy Towers
Dalal Street
Mumbai 400 023
Scrip Code – 524494

National Stock Exchange India Limited,
Exchange Plaza, C-1, Block-G,
Bandra Kurla Complex, Bandra – (East).
Mumbai-400051.
Scrip Code : IPCALAB

Sub: Media Release

Dear Sir,

We are enclosing herewith the media release issued by the Company w.r.t launch of patented novel drug branded as “Diulcus[®]” in the Indian market for treatment of Diabetic Foot Ulcer (DFU). Currently there is a global unmet medical need for treatment of DFU which is the most prevalent complication caused by chronic diabetes.

Thanking you.

Yours faithfully

For Ipca Laboratories Limited

Harish Kamath
Corporate Counsel & Company Secretary

Ipca Laboratories Ltd.

www.ipca.com

125, Kandivli Industrial Estate, Kandivli (West), Mumbai 400 067 (Maharashtra), India | T: +91 22 6210 5000 F: +91 22 6210 5005

Regd. Office: 48, Kandivli Industrial Estate, Kandivli (West), Mumbai 400 067 (Maharashtra), India | T: +91 22 6647 4444

E: ipca@ipca.com CIN: L24239MH1949PLC007837

6th August, 2024

NovaLead's Patented Repurposed Drug receives permission from CDSCO for the treatment of Diabetic Foot Ulcer (DFU) for Indian market – to be marketed by Ipca Laboratories Ltd. (Ipca) under brand name Diulcus[®]

The permission is based on Phase III study which established that NovaLead's patented drug branded as Diulcus[®] promotes the complete closure of DFU significantly better than the Standard of Care, which is the present treatment of choice. Currently there is a global unmet medical need for the treatment of DFU.

With over 15% of diabetic patients suffering from DFU at least once in their lifetime, DFU is the most prevalent complication caused by chronic diabetes. The permission of this patented repurposed drug is significant because DFU is the leading cause for lower limb amputations globally.

The permission for Diulcus[®] marks a pivotal moment for people suffering from DFU, who until now had few effective drug options for complete wound closure. With 20% higher incidence of complete wound closure among DFU patients demonstrated in its pivotal Phase III trial over current standard of care, Diulcus[®] provides significantly superior treatment option to physicians treating DFU patients. Permission for Diulcus[®] is also a demonstration of effective Public-Private partnership as its development was part funded through Grant-In-Aid from BIRAC, a Government of India initiative.

Diulcus[®] is a novel topical formulation of an active pharmaceutical ingredient which was originally approved for the treatment of Tachycardia as an intravenous injection. NovaLead has been granted patents for it in several countries including regulated markets of USA, EU and Japan.

Diulcus[®] will be made available to the patients of DFU by Ipca through an exclusive IP licensing arrangement with NovaLead for Indian market.

“We are delighted to partner with NovaLead through an IP licensing arrangement to bring Diulcus[®] for DFU patients in India. It demonstrates Ipca's commitment towards the patients suffering from unmet medical need of DFU management and its focus on the diabetes sector. We are lining up for making Diulcus[®] available in India market from August, 2024.” Said Mr. Premchand Godha, Executive Chairman of Ipca Laboratories Ltd.”

About Diabetic Foot Ulcer (DFU)

Over 537 million adults are living with diabetes globally and the number is predicted to rise to 643 million by 2030. About 15% of diabetics suffer from DFU, at least once in lifetime, with 25% of DFUs eventually requiring amputation. DFU is a leading cause of lower extremity amputation. The five-year mortality post amputation is 46%. DFU is a serious disease with very limited drug options and very high cost of treatment.



About Diulcus[®] (Esmolol Hydrochloride)

Diulcus[®] is a prescription medicine used to treat people with diabetic foot ulcer with no clinical infection. Infected DFUs need to be first treated for infection if existing and then put on Diulcus[®] treatment for wound closure. A doctor will perform independent assessment of DFU extent to determine the dose to be applied topically on the patient's DFU. Treating clinicians are advised to refer to the full prescribing information of Diulcus[®].

About Ipca Laboratories Ltd.

Ipca is a fully integrated pharmaceutical company with a strong thrust on exports. Ipca is vertically integrated and produces Finished Dosage Forms (FDFs) and Active Pharmaceutical Ingredients (APIs).

Prashant Godha
Executive Director

For more information :

Ipca Laboratories Ltd
Dr. Anil Pareek
President - Medical Affairs & Clinical Research
anil.pareek@ipca.com