## Press Release Details

Title 15 Jul 2005 Bharat Biotech launches REGEN–D

## **Details**

Bharat Biotech launches REGEN-D – a specialized therapeutic for Diabetic Foot Ulcers, Burns & Skin Grafts Bharat Biotech's REGEN-D to revolutionize treatment for Diabetic Foot Ulcers, I & II Degree Burns and Donor Site Skin Grafts Chennai, July 15, 2005: Bharat Biotech International Limited set a precedent in the arena of Diabetic Foot Care, Burn Injuries and Skin Grafts by launching a path-breaking therapeutic - REGEN-D, India's First Recombinant Epidermal Growth Factor (rhEGF).

Dr. N. K. Ganguly, Director-General, Indian Council of Medical Research formally launched the country's first Recombinant Epidermal Growth Factor - REGEN-D, indigenously developed, and manufactured by Bharat Biotech in Chennai on Friday.

Speaking on the occasion, Dr. Ganguly said "REGEN-D is the result of a unique public – private technology collaboration that will change the lives of Diabetic and Burn patients forever." Bharat Biotech developed this extraordinary therapeutic REGEN-D in collaboration with the Institute of Genomics and Integrated Biology (IGIB) New Delhi.

Bharat Biotech is introducing REGEN–D in two strengths; REGEN–150 for Diabetic Foot Ulcers and REGEN–60 for Burns and Skin Grafts.

Speaking on the occasion, Dr. Krishna M. Ella, the Chairman and Managing Director of Bharat Biotech said, "According to the estimates of World Health Organisation (WHO), diabetes will become one of the world's main disablers and killers within the next twenty-five years. The WHO's latest estimate for diabetes patients world-wide, in 2000 is 177 million. Around 3.2 million deaths every year are attributed to complications of diabetes; in India alone, patients undergo 40,000 amputations every year due to Diabetic Foot Ulcers. In this context REGEN–D 150 manufactured indigenously will tremendously impact the lives of Indian population affected with Diabetic Foot Ulcers."

Dr. Vijay Vishwanathan, Joint Director MV Hospital for Diabetes & Diabetes Research Centre in his presentation said "Treatment of Diabetic Foot Ulcers is expensive making it out of reach for common people. In US, treatment for Diabetic Foot Ulcers may cost anywhere between 4000 – 5000 USD per month. The same therapy in India is also available at approximately Rs.25,000, per month. Bharat Biotech's REGEN-D 150 now available in India will provide succor to many suffering with Diabetic Foot Ulcers."

Dr. K. Mathangi Ramakrishnan, Chairperson CHILDS Trust Medical Research Foundation and Secretary, Burns Association of India, in her key note address said that more than 1,20,000 deaths occur due to burns every year in India and therefore management of burn wounds has become a major concern.

"The success rate of effective treatment in India currently ranges between 30 to 55 per cent, compared to 70 and 90 per cent in US and China respectively for victims with 50 per cent burns on their body surface area. Clearly, the need for specific, affordable treatment is the need of the hour. REGEN-D 60 will fill that gap by helping in enhancing healing time for both burns and skin grafts with minimal scarring." she added.

"Women and children are the worst sufferers," said Dr. Mathangi Ramakrishnan. "Heavy scarring due to burn injuries and Donor Site Skin Grafting often results in lack of cosmetic appeal and even in some cases disability. Cosmetic surgery is really expensive and is out of reach for most people. REGEN-D 60 therefore has a great role to play," she noted.

REGEN—D has received all the necessary Regulatory Approvals from Genetic Engineering Approval Committee, Ministry of Environment and Forests and Drugs Control General of India, New Delhi and State Drug Control Administration Hyderabad.

The multi-centric, double-blind, comparative Phase III Clinical study have documented excellent healing rates, well illustrated by the statistical data – P value < 0.005 in case of Diabetic Foot Ulcers, P value < 0.05 for Burn cases and P value < 0.001 in the case of Donor Site Skin Grafts.

The Epidermal augmentation properties have been well documented in developed nations. Bharat Biotech's R&D; Team took up the development of rhEGF molecule for the first time in the country, as they could envisage its impact on the lives of the Indian population, a majority of whom are exposed to conditions such as Diabetic Foot Ulcers, Burn Injuries and other critical surgical interventions.

REGEN-D 150 & 60 are being presented in 7.5, 15 gms in tubes as a topical gel application.