

NovaBay's NeutroPhase receives China FDA nod

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Singapore: The Chinese drug regulatory body, the Food and Drug Administration has provided its approval for NovaBay's NeutroPhase skin and wound cleanser. The company said that it has received the nod to initiate sales of the product and that NovaBay's partner China Pioneer Pharma will be looking into that.

The product is said to help the country cope with wounds associated with diabetes and flesh-eating diseases that are on a constant rise in China.

The biopharmaceutical company further announced that the product will be sold throughout mainland China and that it would be shipping NeutroPhase to china in the fourth quarter of 2014 to support Pioneer's launch of the product in early 2015.

The company added in its announcement that chronic non-healing wounds, such as venous stasis ulcers, diabetic ulcers, and pressure ulcers are serious unmet medical needs that affect a patient's morbidity and mortality.

NeutroPhase is said to have shown remarkable properties in the management of these categories of wounds. Mr Paul Li (Mr Li Xinzhou), Chairman, Executive Director and Chief Executive Officer of Pioneer Pharma said in the statement, "The clearance of NeutroPhase in China will help Chinese doctors address major unmet medical needs. In China, we are experiencing a 'catastrophic' epidemic of diabetes. According to estimates provided by the International Diabetes Federation and the American Medical Association, there are approximately 100 million Chinese already suffering from this condition and its chronic side effects such as diabetic ulcers and other chronic wounds-and their numbers are increasing."

He added, "At the same time, China has the highest number of reported cases of necrotizing fasciitis, or 'flesh-eating' disease of any nation in the world. NeutroPhase will help with both problems."

The company added that NeutroPhase offers new treatment options for both the chronic wounds of diabetes patients and for deadly flesh-eating disease. NeutroPhase contains a substance produced naturally by the immune system as a first defense against microbial invaders. Laboratory tests show that NeutroPhase not only kills bacteria that infect wounds and causes

necrotizing fasciitis, it also neutralizes toxins produced by both bacteria and the immune system that impede healing and destroy healthy tissue. Those properties enable NeutroPhase to address acute infections and thereby help promote the healing of chronic wounds.

"China is a significant market for NovaBay's NeutroPhase. The China FDA approval gives us access to this important market. Pioneer Pharma is a major distributor in the region and is NovaBay's largest single shareholder. We believe that NeutroPhase can bring a major improvement in medical care in China and the quality of these patients' lives," said Dr Ron Najafi, Chairman and CEO of NovaBay.

As part of the partnership deal between NovaBay and Pioneer Pharma, the marketing clearance of NeutroPhase by the Chinese Food & Drug Administration triggers a milestone payment of \$625,000 to NovaBay from Pioneer.