

Biotechnology Havana 2010: Successful healing of Diabetic Ulcers with Heberprot-P

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REPORT

ABSTRACT

Last October 20-22nd, 2010 it was celebrated the 2010 edition to the congress Biotechnology Havana (BH2010) organized every year by the Center for Genetic Engineering and Biotechnology. The BH2010 Conference focused on the Integral Care of Diabetic Foot Ulcer Patients with the Use of Heberprot-P. The Congress was attended by 366 delegates from 36 countries. It was organized in two symposia with 6 plenary lectures, 25 lectures and 120 posters. Symposia were focused on the Molecular biology of growth factors, and the Integral Care to Diabetic Foot Ulcers, Current Status, respectively. The BH2010 lectures were given by representatives of 11 countries from the Americas, Europe and Asia, covering the following issues: Epidermal growth factor, its molecular biology and other molecules used to promote wound healing, clinical experience on using Heberprot-P, therapeutic experience in diabetic foot ulcers and organizational strategies in organizing and extending health services to attend DFU patients. It was evident that Heberprot-P emerged as the unique therapy available to successfully cicatrize Wagner 3-4 DFUs in diabetic patients.

Keywords: diabetic foot, Heberprot-P, Biotechnology Havana

Introduction

The subsequent upraise in the number of Diabetes cases worldwide has gained the focus of international medical and scientific communities on therapies to control this epidemic non-infectious disease. This disease is considered a global non transmitted pandemic affecting more than 290 millions of people throughout the world [1]. Specially, the availability of a therapeutic outcome for diabetic foot ulcer (DFU) treatment other than surgical ablation was forbidden for a long time. In fact, 15% of the overall diabetic patients develop this condition of commonly severe prognosis [2].

Fortunately, the development of Heberprot-P by the Cuban biotechnology industry has finally provided an efficacious treatment to this complication. Heberprot-P is an injectable formulation of the human epidermal growth factor [3] obtained at the Center for Genetic Engineering and Biotechnology (CIGB) of Havana, which is able to be injected at the base of DFUs on metabolically stabilized diabetic patients and regenerates useful granulation tissue leading to epithelialization and closure of DFUs. Most of patients successfully recover, saving their limbs, being DFU treatment the main indication for this pharmaceutical [4]. Heberprot-P is also supported by patents granted in the United States, Europe and other countries, and is currently at the full national extension phase in Cuba [5].

That's why the Biotechnology Havana 2010 conference, held at the Convention Palace in Havana, Cuba, on October 18-19th was dedicated to the *Integral Care to Diabetic Foot Ulcer Patients with the Use of Heberprot-P* [6].

The training course

BH2010 was preceded by a practical training course-workshop on the diabetic patient care and proper application of the product, held on October 17-18th at CIGB, bringing attention to the whole metabolic outcome of clinical cases [7]. Noteworthy, 31 specialists from 14 different countries attended to learn how to

treat DFU with this novel product at the introductory course, in spite of other 70 international conferences on diabetes being held at the time. They came from Argentina, Brazil, China, Colombia, Philippines, France, India, Indonesia, Mexico, Ukraine, Russia, South Africa, Venezuela and Yemen, widening the view on this medical condition. Professors were selected among Cuban medical specialists administering the product as part of the Integral Care Attention to Diabetic Patient System of the Cuban Ministry of Health. Most of them stayed for the conference as well.

Clinical criteria, metabolic evaluation and podiatry follow-up were also discussed, aiming at an integral focus on this pathology. All his topics were also supported by instructive video and printed materials [7].

The conference

The conference comprised two symposia: i) Molecular biology of growth factors, chaired by Dr. Jorge Berlanga, from the CIGB; and ii) *Integral Care to Diabetic Foot Ulcers and Global Current State*, chaired by Dr. José Ignacio Fernández Montequín, from the National Institute of Angiology and Vascular Surgery (INACV) [6]. Up to 6 plenary and 25 standard lectures, and 120 posters were presented at the Conference. Lectures addressed the development of the product as part of the Cuban biotechnology industry. Nineteen out of the 31 lectures were related to Heberprot-P. Regarding the topic, there were 13 lectures on therapeutic experiences, 3 on clinical trials, 10 emphasized on organizational strategies for attending DFU patients and 5 on human epidermal growth factor molecular biology and other molecules which promote healing.

The Cuban experience was overwhelming, already showing results from the full national coverage of diabetic patients suffering from this condition. Significantly, it was a fact that the amputation score diminished after administering Heberprot-P in patients bearing Wagner 3-4 lesions, while successful recov-

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7. Practical Application of Heberprot-P in Diabetic Foot Ulcer Patients. Pre-Congress Course-Workshop [Internet]. Havana: Center for Genetic Engineering and Biotechnology; c2010 [updated 2010 Oct 17; cited 2011 May 10]. Biotechnology Havana 2010; [about 4 screens]. Available from: http://bh2010.cigb.edu.cu/index.php?option=com_content&view=article&id=38&Itemid=30&lang=en

ery was evidenced in cases of Wagner 5 lesions [8]. Nevertheless, other experiences including the clinical combination of surgical debridement together with preparation of surgical beds were presented. Session discussions also emphasized on the essential multidisciplinary management of these type of patients. Specific clinical scenarios, as that of the Charcot foot, coverage of cancellous bone, tissue regeneration, were discussed. Other alternative treatments using skin-graft were presented [9]. An overall tendency on this field was proposed, concerning future perspectives for development. Undoubtedly, Heberprot-P emerged as the treatment of choice, due to a direct and predictable incidence on the lesions [8].

The poster session brought full coverage of scientific developments regarding pharmacogenomics and mass spectrometry for Heberprot-P characterization, biological assay for activity validation of Heberprot-P, its quality controls, reference materials and stability studies, developments for control release and post-marketing studies. A significant number of works focused on clinical cases of DFUs treated with Heberprot-P (either neuroinfectious, ischemic or both), its impact on amputation scores, results from treatment extension, and some presentations of other similar treatments and product presentations.

It was a consensus among the 366 delegates from 11 countries at the Conference that Heberprot-P substantially increases the opportunity of preserving the limb among diabetic patients having DFUs. Indeed, poster sessions included many reports of successfully-treated DFU patients mainly from Cuba and Venezuela, showing the positive impact of the national extension program of Heberprot-P therapy in Cuba, currently extended to 49 Cuban hospitals and 91 polyclinics disseminated in all Cuban provinces and in Venezuela as well.

The Conference also brought printed informational support on the product as flyers, product brochures, and the Conference proceedings in CD-ROM were launched together with an issue of the *Biotecnología Aplicada* journal, entirely dedicated to the topic.

In parallel with the BH2010, an international Fair was run offering the opportunity to 14 different international organizations to expose their main products linked to diabetes, research, biotech and health sectors, also helping medical leaders to analyze potential business interactions and commercial transactions.

In summary, the BH2010 Conference showed one of the pinnacles of the Cuban biopharmaceutical industry, focused on a unique product worldwide and a very specific and widespread pathology. In fact, it regained the tradition started by the Interferon congresses of Biotechnology Havana-product oriented conferences. On its first edition, the BH2010 dedicated to Heberprot-P helped to disseminate these out-standing scientific result, which was recently awarded as a significant achievement by the World Intellectual Property Organization (WIPO) Gold Medal [10].

The main results of the Conference were: i) Results shown in and derived from BH2010 activities will contribute to improve the quality of life of DFU patients with the participation of all congress delegates; ii) the impressive positive impact of the extension of Heberprot-P therapy in Cuba and Venezuela were discussed, showing its results in promoting the healing in DFUs patients; and iii) Cuban health authorities proposed to maintain the subject of this type of meeting, giving birth to a series of Congress that will focus in the treatment of DFUs every two years.

All these highlight the great compromise of the Cuban Health System with the wellbeing of the people, and the interest to solve significant health problems of the entire human mankind.

You are all welcome back to the second Biotechnology Havana conference, as planned to be held in Havana in November 22-26th, 2012, as part of a series of conferences on Integral Care of Diabetic Foot Ulcers with the use of Heberprot-P [11]. It will preserve the same design of a pre-congress course-workshop, together with three days fully dedicated to recent advances and treatment. Your contribution, experience and participation will be essential.

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