

Perspective

Transcontinental Translational Medicine Collaboration: A Successful Sino-Cuban Joint B-to-B Program

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Translational medicine is a comprehensive discipline that aims to convert laboratory research results into products and technology for clinical application using modern molecular biological techniques, to improve our understanding of the human body and disease and to optimize laboratory design for clinical observation and analysis for basic research. Its ultimate goal is improving holistic medicine and helping patients solve their health problems. Translational medicine includes two processes: bench to bedside and bedside to bench, known as B-to-B processes. The first B-to-B (bench to bedside) refers to the application of results of the laboratory to clinical use as a medical product or a diagnosis and treatment technology. The second B-to-B (bedside to bench) describes the process by which clinical observation and analysis provides ideas and guidance for experiment design for basic medical research. The two processes complement each other and constitute the two-way cycle of translational medicine. Translational medicine can be applied to clinical disease detection in the form of new biomarkers and can accelerate drug discovery. In recent years, with the rapid development of biotechnology, increasing outcomes of research on molecular pathogenesis can be directly applied to clinical therapy.

In two decades of development, by the application of translational medicine, the cooperation between China and Cuba in the field of biotechnology has made positive progress in scientific research, cooperation, and team building. Features of this cooperation are a solid foundation, rich content and firm relationship. According to the *Sino-Cuban* Memorandum of Understanding on Cooperation in the Field of Biotechnology (hereafter referred to as the 2004 Memo), and the *Sino-Cuban* Memorandum of Understanding on Further Strengthening Cooperation in the Field of Biotechnology (hereafter referred to as the 2009 Memo), cooperation between China and Cuba follows a development plan

established by the two countries. A Meeting of the *Sino-Cuban* Joint Working Group on Biotechnology Cooperation has been held seven times between 2004 and 2013, playing an important role in promoting cooperation in the field of biotechnology and motivating economic and social development on both sides.

In 1981, Cuba set up a biology research center, and subsequently launched a series of biotechnology research centers. With the support of the Cuban government, it has become a world superpower in the field of biotechnology. The release of biological medicines and biological vaccines, which are completely independent products of research and development with independent intellectual property rights, has benefited domestic health care sectors and achieved remarkable results in terms of exports. On November 27, 2012, a meeting of Cuban ministers approved the 307th order on the establishment of an Cuba technology and pharmaceutical industry group (BIOCUBAFARMA). The group was integrated in a science park (POLO CIENTIFICO) and the subordinate agency of a biochemical pharmaceutical group (QUIMEFA). The main task of this group is manufacturing high-tech pharmaceuticals and medical equipment and providing medical care. Its purpose is to safeguard population health and supply export products and services. The group comprised senior management agencies and 38 companies operating under the enterprise principle.

In China, the government attaches great importance to the development of biotechnology. It has been ranked as the first item in the “863 plan” and has been incorporated into a national key research project. These steps have greatly promoted the development of medical biological technology in China. In China, research on and manufacture of genetically engineered polypeptide pharmaceuticals, monoclonal antibodies, and new diagnostic reagents has been conducted on the basis of imitation, and is on the way of innovation and development. At

present, China is able to produce most of the genetically engineered polypeptide medicines in the international market. Research on genetically engineered vaccine development has also made rapid progress. The launch of a genetically engineered hepatitis B vaccine has played a very important role in the prevention of hepatitis B. A bivalent dysentery vaccine and a cholera vaccine have been approved for trial production, and schistosomiasis and hemorrhagic fever vaccines are in clinical trials.

In recent years, by application of translational medicine, the two countries have been cooperating closely in the field of biotechnology for mutual benefits. In the cooperation between China and Cuba, the monoclonal antibody medicine Nimotuzomab, made by Biotech Pharma, has been granted the national class I medicine certification and placed in the Chinese market in 2008, and has been administered to over 10 000 patients. According to test results from the Cuban molecular immunology center, 87.5% patients with terminal nasopharyngeal carcinoma (NPC) have experienced "complete remission" after treatment, doubling the percentages achieved by conventional radiotherapy and chemotherapy. The interferon cooperation project between Heber and the Cuban biotechnology and genetic engineering research center (CIGB) could achieve an annual output of 10 million human recombinant interferon doses. In July 2007, the project received a GMP certificate issued by the China Food and Drug Administration. The glucose meter cooperation project between Changsha Sannuo and the Cuban immunoassay center (CIE), furnishes Cuba with production capacity of new products for diabetes control, which are made available in the third-country market. In 2013, sales contracts in the Cuban market totaled to approximately 30 million yuan.

Biotech Pharma Co., Ltd, a *Sino-Cuban* joint venture, was founded in 2000. After more than ten years of unremitting technological innovation, the company has built the largest and most advanced humanized monoclonal antibody medicine research, development, and industrialization base in the economic and technological development zone in Beijing. At present, Biotech Pharma has grown into a leader in the field of antibody medicine and has won industry recognition and praise. Because the two countries signed the joint venture agreement in 1999, Biotech Pharma has already exploited the first humanized monoclonal antibody medicine, Nimotuzomab, in China, together with the Cuban

molecular immunology center, and the obtained drug was issued a national class I medicine certification by the China Food and Drug Administration in April, 2005. Nimotuzomab has been mainly used in the treatment of head and neck cancers, colorectal cancer, gastrointestinal cancer, neuroglioma, non-small cell lung cancer, breast cancer, and other cancers. Nimotuzomab was launched in 2008, with an annual sales growth of approximately 40%. In 2012, single-variety sales reached 400 million yuan. At present, Biotech Pharma and the Cuban molecular immunology center are jointly conducting several new biological medicine projects, including EGF peptide coupling vaccines for cancer treatment and Itolizumab for treating rheumatoid arthritis and other autoimmune diseases. The two projects are under clinical study, phase I, clinical research is expected to be completed in the upcoming 3-5 years, and the outcome will benefit patients with tumors and autoimmune diseases in China. To implement the "*Sino-Cuban* biological medical cooperation framework agreement," and enhance *Sino-Cuban* cooperation in the field of biotechnology, Biotech and the Cuban molecular immune center launched the "14F7 humanized antibody medicine project" in 2013. The development of these cooperative projects help the development of biotechnology serve the Chinese people and improve the research and development level of biopharmaceuticals with marked social and economic effects in China.

Cooperation between the Chinese CDC and the Cuban Ministry of Public Health on personnel training and exchanges in fields such as vaccines, AIDS, tuberculosis, hepatitis prevention and control, and tropical diseases should be further enhanced, and communication of information on prevention and control of public health emergency diseases (such as avian influenza and H1N1 influenza) should be strengthened, to enable effective support of biotechnology for public health. To improve the efficiency of cooperation in the framework of the existing laws and regulations, support of both governments for application of biotechnology in the clinical field should be further strengthened. For example, population-based health interventions in cancer control using biotechnological products, management of head and neck and esophageal cancers using monoclonal antibodies, and lung cancer using therapeutic vaccines. There is also the possibility of a wider intervention in liver disease combining Cuban diagnostic systems, the hepatitis B vaccine, interferons, and monoclonal antibodies.

As a new and comprehensive discipline, biotechnology is playing an increasingly important role in diagnosis, prevention, control, and eradication of infectious diseases as well as protection of human

health. Biotechnological cooperation between the two countries will bring mutual benefits to both countries and globally set a good example to promote multilateral cooperation.

中古生物技术合作联合工作组第七次会议
La séptima reunión del grupo de trabajo conjunto de la
cooperación biotecnológica de China y Cuba

