

## **Orient Pharma received “Accreditation Certificate of Foreign Drug Manufacturer” from Japan Ministry of Health, Labour, and Welfare**

(May 25, 2012) Orient Pharma focuses on R&D and manufacturing, and values profession and quality. In addition to the approval for PIC/S GMP from Taiwan FDA, we received “Accreditation Certificate of Foreign Drug Manufacturer” from Japan Ministry of Health, Labour, and Welfare (MHLW) in April, 2012. Japan MHLW set very high standards for pharmaceutical manufacturing process and product quality. This accreditation assures Orient Pharma’s manufacturing instruments and processes to be in compliance with international standards and recognized by developed countries. In addition, it also signifies that Japan opens the market to Orient Pharma, and that our products can be exported to Japan after receiving product approval.

Orient Pharma Yunlin plant was designed to conform to the standards set forth by WHO PIC/S GMP, EU GMP, and US FDA 21CFR. The air conditioning system, pure water system, air compress system, and maintenance and repair system were constructed based on the future trend and needs, to prevent cross-contamination to the plant and equipment. This plant is one of the pharmaceutical plants with prospective design in Taiwan. Orient Pharma actively applies for product certification from foreign countries. Currently, US FDA has accepted our application, and we expect their plant inspection to be conducted in Taiwan by the end of 2012. As to the next step, Orient Pharma will apply for product certification from Europe and Japan, to earn the opportunities to manufacture patented products with new formulation.

Orient Pharma actively invests in R&D and manufacturing in pharmaceutical products with new indications, new formulations, and new chemical entities. Current R&D plans include microgranules, multi-staged controlled release technology, trans-dermal patches, oral disintegrating tablets, and sustained-release technology. In addition, Orient Pharma is actively cooperating with well-known foreign pharmaceutical companies to develop new drugs, and have signed a contract with Summit, a noted British biotechnology company, to develop a drug for treating hypersalivation in patients with Parkinson disease. Moreover, it is working together with C5Rx, a US company, to develop a world patented anticancer drug that contains a new composition. Furthermore, many ongoing R&D plans are conducted through collaboration with local and foreign research organizations, including new chemical entity in treating breast cancer and new formulation in treating Attention Deficit Hyperactivity Disorder (ADHD).