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 1: [Curr Opin Investig Drugs](#). 2002 May;3(5):698-707.[Links](#)**Thymosin alpha1. SciClone Pharmaceuticals.****[Billich A.](#)**Novartis Research Institute, General Dermatology, Vienna, Austria.  
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Thymosin alpha1 (Talpha1), a synthetic 28-amino acid peptide with multiple biological activities primarily directed towards immune response enhancement, was originally developed by Alpha 1 Biomedicals for the treatment of hepatitis B virus (HBV) infection. SciClone developed and launched Talpha1, under the trade name Zadaxin, for the treatment of HBV and hepatitis C virus (HCV) infections. The drug is also being developed for the treatment of non-small cell lung cancer (NSCLC), hepatocellular carcinoma, AIDS and malignant melanoma. Talpha1 is able to potentiate the action of cytokines and also reduce the hematological toxicity of cytotoxic drug therapy (cyclophosphamide-, 5-fluorouracil-, dacarbazine- or ifosfamide-based regimens). These studies also demonstrated the mechanism of action of Talpha1 and its role as an immune system enhancer. By July 2001, it was in phase III trials in the US in combination with PEGylated interferon-alpha, and later the same month it was approved in the Philippines. SciClone received expanded approval for HBV and HCV infection in Mexico in July 2001. Talpha1 has been launched in Argentina, China, Peru, the Philippines and Singapore for the treatment of chronic HBV infection. The product subsequently received expanded approval for the treatment of both HBV and HCV infection in Argentina. Marketing approval was granted in India for HBV infection in February 2001. The company was working to expand this approval to include HCV infection. In March 2000, approval for treatment of HBV infection was granted in Thailand, Laos and Malta. Approval was also granted in Sri Lanka and Brunei in August 1999. In September 2000, SciClone announced that approval had been expanded to include the treatment of HCV infection as well as the previously approved HBV indication in both Peru and Sri Lanka. In January 1999, SciClone received approval for Talpha1 in Venezuela for the treatment of HBV and HCV infection. The company also filed a marketing application in New Zealand for Talpha1 to treat HBV infection. The drug was approved in South Korea in April 2000, as an influenza vaccine adjuvant and this was expected to be expanded to include use for treatment of both HBV and HCV infections. In July 2001, it was approved in In September and October 2000, SciClone was granted patents in Mexico and Canada, respectively, for the use of Talpha1 for the treatment of HCV infection. In June 2000, SciClone was issued a Notice of Allowance by the US Patent and Trademark Office for use of Talpha1 in the treatment of HBV infection. The EPO granted a patent, exclusively licensed to SciClone, for the use of Talpha1 as a monotherapy or in combination with interferon, to treat for HCV infection. In April 2001, SciClone received a Notice of Allowance for a US patent covering newly described analogs of Talpha1. The patent gave the Philippines as an adjuvant to chemotherapy for the treatment of various cancers. In December 2001, Talpha1 entered a phase 1 trial program in Europe, with patient enrolment planned for 2002. SciClone exclusive composition-of-matter rights to several families of Talpha1 analogs that could have proprietary therapeutic or biologic distinctions from Talpha1. The company was issued US patents covering the use of Talpha1 for the treatment of HCV infection in August 1998 and the treatment of HBV infection in September 1999. A Notice of Allowance for a second US patent covering the use of Talpha1 was issued in October 1999. In April 1999, SciClone received allowance of a patent from the EPO covering the use of Talpha1 in small cell and non-small cell lung cancer. In August 2001, SciClone received a notice of allowance for patent protection in Japan covering the use of Talpha1. The patent, which extends until 2012, also covers the use of Talpha1 in combination with interferon-alpha for the treatment of HCV infection. SciClone was previously granted a Japanese patent for the use of Talpha1 in the treatment of HBV infection.

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