

In trial MDT3-003, Labopharm's once-daily formulation of tramadol achieved statistical significance for the three coprimary endpoints, which were reduction in pain, improvement in physical function, and patient's global assessment of the product's effectiveness.

In trial MDT3-002, while once-daily tramadol demonstrated a similar improvement in pain relief, physical function, and patient's global assessment, due to an unusually high response to placebo, statistical significance was not demonstrated for all of the three coprimary endpoints. The two studies enrolled approximately 1100 patients. Additionally, in both trials, Labopharm's once-daily tramadol provided full 24-hour pain relief and exhibited an adverse events profile clinically superior to that of the immediate release formulation of tramadol as reported in the literature.

These study results, together with the results from Labopharm's European phase III clinical trial for once-daily tramadol, will form the basis of a new drug application (NDA) with the U.S. Food and Drug Administration.

"We have completed three phase III clinical trials, involving more than 1500 patients, in which Labopharm's once-daily tramadol has demonstrated a reduction in pain, an improvement in physical function, and a reduction in adverse events. This data provides us with a strong clinical package for the NDA filing, despite not having achieved statistical significance in one of the U.S. studies," said James R. Howard-Tripp, president and CEO, Labopharm, Inc. "We believe strongly in the potential for our once-daily formulation of tramadol and our global commercialization plan remains on track."

Tramadol is a centrally acting analgesic indicated for moderate-to-moderately severe pain that may be associated with conditions such as osteoarthritis, lower back spasm, cancer, and other acute and chronic conditions.

This article was prepared by Medical Letter on the CDC & FDA editors from staff and other reports. Copyright 2004, Medical Letter on the CDC & FDA via NewsRx.com.

Antimicrobials

Antimicrobials isolated from *Salvia* and *Eucalyptus* species

2004 FEB 29 - (NewsRx.com) -- According to a study from Russia, "The mechanism of action of quinones from the roots of *Salvia officinalis* L. (royleanones) and terpenoid phenolaldehydes from the leaves of *Eucalyptus viminalis* Labill. (euvimals) was studied."

"Royleanones and euvimals displayed marked protonophoric activity on artificial bilayer lipid membranes in vitro, and exerted an uncoupling action on oxidative phosphorylation in isolated rat liver mitochondria," reported Nikolay A. Spiridonov and colleagues at the Russian Academy of Sciences. "The results suggest that biological membranes are the primary targets of royleanones and euvimals, and the protonophoric activity may contribute to the cytotoxicity and antimicrobial properties of these compounds."

Spiridonov and his coauthors published their study in *Phytotherapy Research* (Protonophoric and uncoupling activity of royleanones from *Salvia officinalis* and euvimals from *Eucalyptus viminalis*. *Phytother Res*, 2003;17(10):1228-1230).

For more information, contact Nikolay A. Spiridonov, Center for Biologics Evaluation and Research, Food and Drug Administration, HFM-541, Building 29A, Room 3B-20, 29 Lincoln Drive, Bethesda, MD 20892, USA. E-mail: spiridonov@cber.fda.gov.

Publisher contact information for the journal *Phytotherapy Research* is: John Wiley and Sons Ltd., The Atrium, Southern Gate, Chichester PO19 8SQ, West Sussex, UK.

The information in this article comes under the major subject areas of Antimicrobials, Anti-Infectives, and Pharmaceutical and Drug Development.

This article was prepared by Medical Letter on the CDC & FDA editors from staff and other reports. Copyright 2004, Medical Letter on the CDC & FDA via NewsRx.com.

Avian Influenza

Asia should stockpile bird flu drugs

2004 FEB 29 - (NewsRx.com) -- Countries should consider stockpiling antiviral drugs in case the bird flu striking Asia's poultry becomes equally contagious among people, the World Health Organization (WHO) says.

Indonesia, meanwhile, warned that it could lose a million jobs because of the avian influenza, and China, stung by criticism of its slow response to SARS last year, ordered its officials to act quickly to inform people about the outbreak.

The deadly virus is highly contagious among poultry, and millions of birds have died or have been destroyed in efforts to contain it.

Although the virus has killed people in Vietnam and Thailand, so far there have been no reports of human-to-human transmission, with all cases traced to direct contact with sick birds.

Health experts fear that if avian influenza strikes someone suffering from human flu, the viruses could create a hybrid as deadly as bird flu and as contagious as human flu. That could cause a deadly global pandemic, the WHO has warned.

Because a vaccine for humans is many months away, and might not be widely available at first, countries need to consider stocking antiviral drugs, Klaus Stohr, WHO's chief flu expert, said.

Some countries already are negotiating with companies to supply the drug, and Japan wants 40 tons of the drug, Stohr said.

The World Health Organization also said that some workers in parts of Asia are not wearing adequate protective gear as they slaughter contaminated birds.

Indonesia, which had insisted that large-scale slaughter of chickens was not necessary, reversed that decision and ordered a mandatory mass cull of poultry in infected areas.

Sofyan Sudrajad, an Agriculture Ministry official, said that the outbreak could leave 1.25 million people jobless and cost the country \$916 million. Japan, a big chicken customer, has banned Indonesian imports.

Vietnam said it may be necessary to destroy all the chickens in the country.

Thailand also said that bird flu has been found in poultry in a province bordering the popular tourist resort of Phuket, the first time the virus has been detected in the country's south.

China confirmed cases of bird flu in poultry in two central provinces and said it was investigating suspected cases in three other regions.

The State Council, China's Cabinet, set up a national command center to battle bird flu and named a vice premier to run it. The move came a day after Premier Wen Jiabao issued an eight-point directive instructing agencies to deal with the problem aggressively.

Copyright of Medical Letter on the CDC & FDA is the property of NewsRx and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.