

Form 51-102F3

MATERIAL CHANGE REPORT

1. Name and Address of Company:

Axcan Pharma Inc. (the "Company")
597, boul. Laurier
Mont-Saint-Hilaire, Quebec
J3H 6C4

2. Date of Material Change:

December 15, 2004

3. News Release:

Press Release issued on December 15, 2004 through CNW.

4. Summary of Material Change:

The Company announced positive cardiac safety results of a high dose (supratherapeutic) study for the new prokinetic agent, ITAX™ (Itopride hydrochloride). In this study, ITAX had no clinically relevant effects on heart rate, cardiac conduction and cardiac repolarization.

The Electrocardiogram ("ECG") trial was intended to determine the cardiotoxicity potential of Itopride. The study used a single-site, randomized, placebo and positive controlled, parallel designed, steady state (5 days), multiple dose trial. The study involved 162 healthy male and female volunteers aged 18-45 years. Itopride at 100 mg three-times-a-day and at a supratherapeutic dose of 400 mg three-times-a-day was compared to placebo and moxifloxacin, an antibiotic that produces a 5-10 ms effect on cardiac repolarization as defined by changes in the individually corrected QT interval (QTcI).

The study as conducted, confirmed an expected 8 ms placebo-corrected QTc prolongation in the moxifloxacin group. Conversely, Itopride, at clinical and supratherapeutic doses showed a 1 and 2 ms placebo corrected change and 2 and 3 ms using the maximum QTcI duration derived by taking the longest interval at any time point in each subject. Therefore, the variation in QTc for the Itopride groups was well within the 5 ms safety margin considered by experts as having no impact on cardiac safety. (*Draft Guidelines on Clinical Evaluation of QT interval prolongation – 2002- FDA web-site*). Thus, there were no clinically relevant effects of Itopride on heart rate, cardiac conduction (PR and QRS duration) or cardiac repolarization (QTcI). In light of these results in healthy volunteers, Itopride does not appear to affect the QTc interval.

5. Full Description of Material Change:

See item 4 and attached press release

6. Reliance on subsection 7.1(2) or (3) of National Instrument 51-102:

Not applicable

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7. Omitted Information:

None

8. Executive Officer:

Julie Thibodeau

Manager, Investor Relations

Axcan Pharma Inc.

Tel: (450) 467-2600 ext. 2062

9. Date of Report:

December 16, 2004



AXCAN PHARMA INC.

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SOURCE:

AXCAN PHARMA INC.

TSX SYMBOL (Toronto Stock Exchange):
NASDAQ SYMBOL (NASDAQ National Market):

AXP
AXCA

DATE:
Press Release for immediate distribution

December 15, 2004

Axcan's High Dose Safety Study on ITAX in Healthy Subjects Shows No Cardiac Adverse Drug Reaction

Results of a large, high dose, electrocardiogram trial completed in 162 healthy subjects

Axcan will host a conference call Wednesday, Dec. 15, at 9:00 A.M. E.T.

MONT SAINT-HILAIRE, Quebec – Axcan Pharma Inc. ("Axcan" or the "Company") announced positive cardiac safety results of a high dose (supratherapeutic) study for the new prokinetic agent, ITAX™ (Itopride hydrochloride). In this study, ITAX had no clinically relevant effects on heart rate, cardiac conduction and cardiac repolarization.

"We are extremely pleased that this important safety study has indicated that Itopride (ITAX) tablets, even at four times the intended therapeutic dose, have shown no toxic effects on the heart," said Léon F. Gosselin, President and Chief Executive Officer of Axcan. "After having achieved this important milestone, we can now fully focus on executing the Phase III clinical trial program to demonstrate its safety and effectiveness in treating functional dyspepsia."

SUPRATHERAPEUTIC STUDY SUMMARY AND RESULTS

The Electrocardiogram ("ECG") trial was intended to determine the cardiotoxicity potential of Itopride. The study used a single-site, randomized, placebo and positive controlled, parallel designed, steady state (5 days), multiple dose trial. The study involved 162 healthy male and female volunteers aged 18-45 years. Itopride at 100 mg three-times-a-day and at a supratherapeutic dose of 400 mg three-times-a-day was compared to placebo and moxifloxacin, an antibiotic that produces a 5-10 ms effect on cardiac repolarization as defined by changes in the individually corrected QT interval (QTcI).

An expert centralized ECG laboratory analyzed more than 13,000 digital ECGs using a high-resolution manual on-screen caliper method with annotations. All subjects received placebo on day 1 in a single-blind fashion. ECGs were recorded using a digital continuous 12-lead (H-12) system over 24 hours at baseline and steady state.

The study as conducted, confirmed an expected 8 ms placebo-corrected QTc prolongation in the moxifloxacin group. Conversely, Itopride, at clinical and supratherapeutic doses showed a 1 and 2 ms placebo corrected change and 2 and 3 ms using the maximum QTcI duration derived by taking the longest interval at any time point in each subject. Therefore, the variation in QTc for the Itopride groups was well within the 5 ms safety margin considered by experts as having no impact on cardiac safety. (*Draft Guidelines on Clinical Evaluation of QT interval prolongation –2002- FDA web-site*). Thus, there were no clinically relevant effects of Itopride on heart rate, cardiac conduction (PR and

QRS duration) or cardiac repolarization (QTcI). In light of these results in healthy volunteers, Itopride does not appear to affect the QTc interval.

"These results suggest that this new prokinetic agent should have no cardiac safety issues related to QTc; indeed, drugs whose maximum effect on QTc interval duration is less than 5 ms at high doses have not so far been associated with 'torsades de pointe' (TDP)," says Dr. Morganroth, a well known cardiologist of the University of Pennsylvania and eResearch Technology, both in Philadelphia.

ABOUT ITAX

ITAX is a patented oral gastropromkinetic drug with antiemetic properties for the treatment of gastrointestinal symptoms caused by reduced gastrointestinal motility. Axcan licensed ITAX from Abbott Laboratories in September 2003. Phase III clinical studies for ITAX are underway in North America and Europe and involve approximately 1000 patients. These Phase III clinical studies are testing ITAX in the treatment of functional dyspepsia, the first indication pursued by the Company.

Itopride Hydrochloride has been marketed in Japan since 1995.

ABOUT FUNCTIONAL DYSPEPSIA

Functional dyspepsia, a disorder of the upper gastrointestinal system, affects up to 25% of the US population annually and accounts for up to 5% of all visits to primary care physicians (*Talley et al Gastroenterology 1992;102;1259-1268*). Currently, there are no known approved drugs for this indication in the United States.

Axcan will host a conference call at 9:00 A.M., on December 15, 2004. Interested parties may also access the conference call by way of web cast at www.axcan.com. The web cast will be archived for 90 days. The telephone numbers to access the conference call are (800) 814-4862 (Canada and United States) or (416) 640-1907 (international). A replay of the call will be available until December 22, 2004. The telephone number to access the replay of the call is (416) 640-1917 code: 21105448.

ABOUT AXCAN PHARMA

Axcan is a leading specialty pharmaceutical company involved in the field of gastroenterology. The Company markets a broad line of prescription products sold for the treatment of symptoms in a number of gastrointestinal diseases and disorders such as inflammatory bowel disease, irritable bowel syndrome, cholestatic liver diseases and complications related to cystic fibrosis. Axcan's products are marketed by its own sales force in North America and Western Europe. Its common shares are listed on the Toronto Stock Exchange under the symbol "AXP" and on the NASDAQ National Market under the symbol "AXCA".

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995.

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward looking and are subject to risks and uncertainties, including the difficulty of predicting FDA and other regulatory approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission and the Canadian Multijurisdictional Disclosure System.

ITAX is a trademark of Axcan or its affiliates.

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