COX-2 Uproar Will Alter Drug Trial Landscape

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Recent events surrounding selective cyclooxygenase-2 inhibitors will have far-reaching implications for future drug trials, Gary S. Hoffman, M.D., said at a symposium sponsored by the American College of Rheumatology.

Drugs under investigation for chronic diseases such as arthritis will require longer trials and follow-up than in the past, in part because of their likely long-term use among the patients who need them. "We can no longer endorse or not endorse these drugs based upon short-term studies, some of which have been as short as 6 weeks or 12 weeks and usually, certainly, less than a year," said Dr. Hoffman, a member of the Food and Drug Administration's arthritis advisory committee.

NSAID trials now will include cardiovascular and thrombotic events among the adverse events they monitor.

But this raises questions as to whether there are other adverse events (AEs) such as cancer, autoimmune effects, or neurocognitive dysfunction that are beyond our current knowledge, said Dr. Hoffman, professor of medicine and chair of rheumatic and immunologic diseases at the Cleveland Clinic Foundation.

"Are we looking at this with blinders on because of recent events or are there other important AEs that we should also be casting a broader net for?" Dr. Hoffman asked. "Perhaps there are increases in malignancies if you follow patients who take drug x, y, or z long enough. How long should those patients be studied in the context of randomized trials?"

Although answers to these questions are lacking, it's obvious that closer premarket drug scrutiny will come at a greater cost, he said.

Forces such as the market, consumers, and the medical community will need to determine how cost-effectiveness will be measured, and ultimately who will pay.

New strategies need to be developed to make new drug studies cost-effective.

Ironically, it was adverse events associated with non-selective NSAIDs that drove the COX-2 market in the first place, he noted. Research suggests that as much as one-third of every dollar spent on NSAIDs goes to managing adverse events. ■

INDEX OF ADVERTISERS

3M Pharmaceuticals
Aldara 30-31

Abbott Laboratories
Corporate 21, 47

Allergan, Inc.
Tazorac 50a-50d, 51

American Express
Business Gold Card 39

Ameripath
Dermpath Diagnostics 73

Astellas Pharma US, Inc.
Corporate 11

Centocor, Inc.
Corporate 20

ChesterValley Pharmaceuticals
Corporate 6, 68

Connectics Corporation
Soroatane 53-55
Olux/Luxiq 62-64

Coria Laboratories, Ltd.
Cloderm 7-8
Salex Lotion 13-14
Salex Cream 27-28
Ovace 71-72

Dermik Laboratories
Benzaclin 35-36

Doak Dermatologics
Keralac Cream 33-34
Selseb 48-50

Galderma Laboratories, L.P.
Cetaphil 41

OrthoNeutrogena
Ertaczo 3-4

Physician's Choice of Arizona, Inc.
Skin Care Products 29

Ranbaxy Pharmaceuticals, Inc.
Sotret 59-60

Stiefel Laboratories, Inc.
Brevoxyl 9-10
Rosac 15-16
Sarna 19
Duac 24-26
Zeasorb 37
Corporate 61

Taro Pharmaceuticals U.S.A., Inc.
Topicort 42-43
Lustra AF 75

Travel Tech Mohs Services, Inc.
Corporate 22

Valeant Pharmaceuticals International
Efudex 17-18
Kinerase 76

Wyeth Pharmaceuticals Inc.
Enbrel 22a-22f