First Anti-Inflammatory Generic Drug Promising New Therapy for Diabetes

Dalia Buffery, MA, ABD

If March 2010 was any indication for the US Food and Drug Administration (FDA)’s intentions, 2010 will witness a good number of generic approvals. Compared with the meager approval record in January (1) and February (2), by March 23 the FDA approved 15 generics in that month alone.

Nevertheless, considering that “the FDA Office of Generic Drugs is stretched too thin,” and that there are “nearly 2000 pending new generic drug applications” waiting to be approved, it is at this pace it would likely take quite some time for all new applications to get through the process. So even though generics currently represent 74% (10% higher than last year) of all drugs dispensed in the United States, this percentage should increase when all these potential generics are finally reviewed by the FDA.

It is perhaps surprising that this whooping just-under three quarters of all medicines sold in the country amounts to only 22% of the dollars spent on prescription drugs, and yet, according to the Generic Pharmaceutical Association, FDA Commissioner Margaret Hamburg said that “the generic pharmaceutical industry saved the federal government and the entire healthcare system about $750 billion over the past decade.” Not bad for a mere 22% of the market share. Can you imagine the savings when generics amount to, say, 35% of the dollar share?

So it was exciting, if unexpected, to see that cost-savings was the motivation for a new clinical trial using a generic drug to cross over clinical therapeutic categories—from one type of inflammatory disease (arthritis) to another (diabetes, which has recently been linked to inflammation). This study may have significant implications for generics and for healthcare cost-savings, especially in light of the rising epidemics of diabetes and obesity. In this 3-month, placebo-controlled, randomized trial (funded by the National Institute of Diabetes and Kidney Diseases) of 108 diabetic patients, salsalate, an anti-inflammatory generic drug normally used for arthritis, has been shown safe and effective for the treatment of type 2 diabetes (and possibly more). Salsalate reduced hemoglobin A1c levels by 0.5%, significantly better than placebo. Other markers of glycemic control also improved with salsalate (as did triglyceride and adiponectin levels).

Investigator Steven Shoelson, MD, PhD, of the Joslin Diabetes Center, said that he and his colleagues approached the federal government, “which has been interested in a safe, effective, and inexpensive new drug for diabetes,” for funding, because “pharmaceutical companies were interested in the idea of an anti-inflammatory drug for diabetes, but not in this compound [ie, generic], because no one can own it.” Lead investigator Allison Goldfine, MD, Director of Clinical Research, Joslin Diabetes Center, and Associate Professor, Harvard Medical School, commented that these results “indicate that salsalate may provide an effective, safe, and inexpensive new avenue for diabetes treatment.” She noted that these results are exciting, and more research is needed (a new phase 3 trial is now under way), adding that “there is reason to think that salsalate also could have beneficial effects on atherosclerosis.”

This study is an unusual feat of innovation in the generic drug arena, motivated by cost-savings rather than cost-gaining (imagine that), with clinicians and researchers charting a new drug development model and potentially new therapeutic directions. Using inexpensive medicines to try to rein in a chronic disease epidemic that is out of control in clinical and costs terms is indeed a novelty. Whether this signals a new trend in the application of generics remains to be seen; it certainly is a welcomed first step in that direction.

References