Microdosing: Updating its role in developing new medicines

January 23 2013

One of yesterday's most promising new tools for speeding the development of new medicines—"microdosing"—has found niches in that process today, and they include uses unanticipated a decade ago. That topic, an update on microdosing, is the cover story in the current edition of *Chemical & Engineering News*. *C&EN* is the weekly newsmagazine of the American Chemical Society, the world's largest scientific society.

C&EN Senior Editor Celia Henry Arnaud explains that microdosing offered promise for helping pharmaceutical companies identify potential failures earlier, before starting full-fledged clinical trials of a potential new drug. It involves giving subtherapeutic doses—1 percent of the full dose—to human volunteers after minimal animal testing. Scientists then would use the results to determine whether to move ahead with expensive safety testing in traditional Phase 1 clinical trials. Microdosing promised to become a standard part of drug development, adding a new so-called Phase 0 to that process.

The article points out that occasional Phase 0 clinical trials do, indeed, take place. But microdosing most often is used in "absolute bioavailability studies," done in parallel with standard clinical trials to determine how much of the drug actually reaches its target tissue to treat the disease. Other uses of microdosing may emerge in the years ahead, the article notes.

More information: "Diverging Roads for

Microdosing"—cen.acs.org/articles/91/i3/Sea … Diverging-Roads.html