BMS-232632

January 1, 2001 By Tim Horn

It’s news when an old dog is up to new tricks. Bristol-Myers Squibb, responsible for the early-’90s nukes d4T and ddI, is barking again, this time about BMS-232632, its first protease inhibitor (PI) slated for Phase III effectiveness and safety studies. What’s new is, compared to current PIs, 632 (the drug’s nickname) lingers long enough in the blood to make once-daily dosing possible.

In a Phase II study of 98 first-time med takers, 632 with BMS siblings ddI and d4T (drug companies love to test combos of their own products -- better data control) reduced viral load by almost a thousand-fold (3 logs) after three months. At nine months, half had undetectable viral loads, about as good as the competition. And while seasoned protease poppers will be glad to hear that cholesterol and triglyceride levels have yet to increase -- good news in light of the high lipid levels seen with other PIs -- those looking for a last-ditch PI will have to wait for more data to see how well 632 works against strains resistant to current classmates.

Project Inform’s Martin Delaney casts a coolish eye on any best-of-breed buzz. “Nine months of treatment is not long enough to know whether this drug will or will not cause lipodystrophy,” he says. “We were not aware of lipodystrophy at similar stages in the early use of a number of other drugs. Only time will tell.”

Another red -- make that yellow -- flag: increased levels of bilirubin (a potential sign of liver problems) in more than half of HIVers on 632. But BMS’ Michael Giordano, MD, says not to panic. The drug appears to trigger a benign disorder called Gilbert’s Syndrome, but only in people who have a latent form of this hereditary condition. “It can lead to occasional episodes of yellowing of the skin and eyes,” Giordano says, “but the liver itself remains normal.”

BMS has not set a date for Phase III trials and won’t speculate on when it hopes to file a New Drug Application with the FDA. If 632 looks interesting to you, call 1.800.TRIALSA.

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