Risky publicity for new statins

With a launch budget of a billion dollars, a clinical development program called "Galaxy", including 16 trials designated Mercury, Stellar, Orbital, Asteroid, Meteor, Jupiter, etc., and the combined efforts of hundreds of respected lipid researchers, regulators, and investigators, who could fail to be impressed by AstraZeneca’s new preparation rosuvastatin?

Yet, closer inspection reveals that this intended blockbuster is nothing more than the sixth statin to be marketed in France (see pages 132-134), and that there is no evidence based on clinical endpoints that it offers cardiovascular prevention. Worse, early safety data call for careful pharmacovigilance because of the risk of rhabdomyolysis and renal toxicity.

More and more opinion-leaders are sounding alarm bells: the editor-in-chief of the Lancet, for example, in an editorial published in October 2003, warned physicians to think twice before prescribing rosuvastatin, and to tell their patients the truth about this drug. And in the United States, the consumer organisation Public Citizen has called on the Food and Drug Administration to withdraw its authorisation of rosuvastatin.

AstraZeneca’s competitors are exploiting this confusion in order to promote their own statins — particularly Pfizer with its front-runner atorvastatin. This unhealthy situation is likely to spawn growing misinformation, inappropriate prescriptions, use of excessive doses, scattering of pharmacovigilance data or even hasty withdrawal from the market: let’s remember the cerivastatin story.

Health care professionals must keep their feet on the ground and remain focused on the best interests of their patients, who have no need whatsoever for rosuvastatin.