Merck’s Victrelis Gets FDA Panel Nod of Approval

April 27, 2011

The committee’s recommendation will be considered by the FDA in its review of the New Drug Application for Victrelis. Though the FDA is not bound by the committee’s recommendation, the agency often acts on the committee’s advice when reviewing new therapies. Merck anticipates a final announcement from the FDA by mid-May.

The advisory committee panel reviewed the results from the Phase III clinical study program for Victrelis, notably the clinical trials HCV SPRINT-2 and HCV RESPOND-2, which included approximately 1,500 patients with chronic HCV genotype 1 infection—the most common form of the virus in the United States and most difficult to treat. Data discussed involved 1,097 treatment-naïve patients (HCV SPRINT-2) and 403 patients who failed previous therapy (HCV RESPOND-2). HCV SPRINT-2 included a separate analysis of results in African-American patients, a patient population that typically does not respond well to standard therapy.

Results from HCV SPRINT-2 and HCV RESPOND-2 were published in the March 31 issue of the New England Journal of Medicine.