BioCentury
THE BERNSTEIN REPORT ON BIOBUSINESS

BioCentury on BioBusiness, Finance

Clean label for Biogen MS drug Tecfidera translates into $3.7B market cap bump

Tecfidera cleans up

-- Erin McCallister

Published on Monday, April 1, 2013

Biogen Idec Inc. (NASDAQ:BIIB) added $3.7 billion to its market cap after **FDA** approved Tecfidera dimethyl fumarate with the cleanest label among oral MS drugs.

Doctors have told BioCentury they like the safety advantage of Tecfidera (BG-12) after Phase III studies showed flushing and abdominal pain as the most common serious adverse events *(see BioCentury, April 18, 2011)*.

Last week, FDA approved Tecfidera for adults with relapsing-remitting MS (RRMS) with a 12-page label that includes just one warning about the potential for lymphopenia. The agency recommends a complete blood count (CBC) test prior to the first dose and annually thereafter. Abdominal pain and flushing are mentioned in the adverse reactions section.

The dimethyl fumarate that activates the NF-E2 related factor 2 (Nrf2) pathway is the third oral MS drug to be approved by FDA. Gilenya fingolimod from **Novartis AG** (NYSE:NVS; SIX:NOVN) was approved in 2010 and Aubagio teriflunomide from the **Genzyme Corp.** unit of **Sanofi** (Euronext:SAN; NYSE:SNY) was approved last September.

Even though Tecfidera is late to the party, doctors last year told BioCentury they would use it first among the oral drugs because of its benign safety profile *(see BioCentury, Oct. 1, 2012)*.

Gilenya's label is 17 pages and lists six different risks under the warnings and precautions section, including decreased heart rate. Doctors are instructed to monitor patients for bradycardia for at least six hours after the first dose. The drug also comes with a REMS to address the cardiovascular risks.

Aubagio's label is 27 pages and includes a boxed warning about the risks of hepatotoxicity and teratogenicity. The drug's label also includes six different risks under the warnings and precautions section and is contraindicated in pregnant women or women of childbearing potential.

Novartis dropped $0.57 to $70.44 and lost $1.4 billion in market cap on March 27, the day Tecfidera was approved, but the pharma ended the week up $0.41 to $71.24 and a market cap of $172.3 billion.

Sanofi dropped $0.39 after Tecfidera's approval to $50.15 and lost $1 billion in market cap, but also was up on the week. It added $0.39 to $51.08 to a market cap of $135 billion.