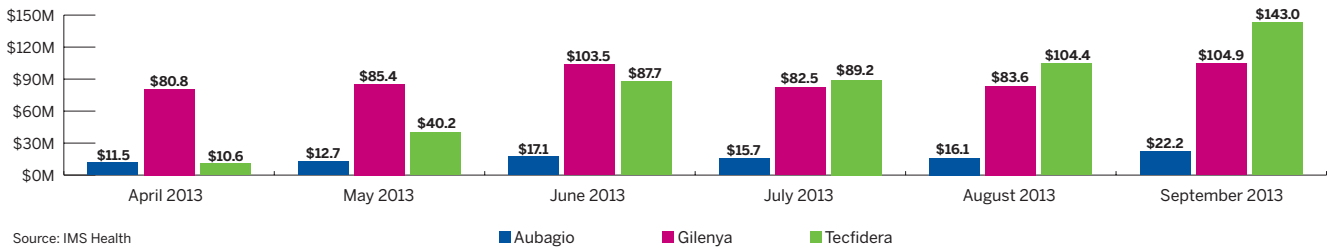


# MS market

## Popular pill

In its first six months on the market, Tecfidera has become the No.-1 prescribed oral therapy for relapsing MS in the US, in terms of total dispensed 'scripts' (18,076, vs. 13,555 for Gilenya and 4,429 for Aubagio in September) and is on-pace to achieve blockbuster sales by early 2014.



In a year when high hopes around several launches ended up fizzling, the hottest launch story belongs to biotech, with the debut of Biogen Idec's Tecfidera pill for the relapsing form of multiple sclerosis (MS).

BG-12, as it was known pre-launch, progressed through late-stage testing with the fanfare of a blockbuster in the making. It passed FDA muster with no black box or monitoring requirements.

That gave it a leg up over Novartis's Gilenya (fingolimod), the pill given the nod in 2010 but which requires new patients to get six hours of monitoring in a doctor's office. Sanofi's Aubagio (teriflunomide), approved in 2012, was shown to lower MS flare-ups by 30%. Again, edge to Tecfidera, whose trial data showed the capsule could cut MS relapses by about 50%.

"Tecfidera meets a lot of unmet need, but in terms of commercializing that innovation," acknowledges Biogen Idec's Deb Glasser, associate director, US commercial, "there were a lot of questions whether [this company] would be able to do that."

Tecfidera (dimethyl fumarate) seems to have answered them. After a three-month FDA delay and approval last spring, it's flourished, satisfying neurologists and analysts.

A patient died in July, but an autop-

## QUICK FACTS ON TECFIDERA

New MS patient starts captured: **One-third\***

Patients on drug: **35,000\*\***

2013 US revenue forecast: **\$779M**

2014 US revenue forecast: **\$1.9B**

2018 global sales forecast: **\$3.2B**

\*First several weeks on market  
\*\*First 6 months on market

Sources: Symphony Health Solutions  
PHAST data, company-compiled sales consensus, inThought Research

For relapsing forms of multiple sclerosis, when it's time to treat, it's time for **Tecfidera** (dimethyl fumarate) delayed-release capsules 240 mg

For more information, please visit [Tecfidera.com](http://Tecfidera.com)

**Indication**  
Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

**Important safety information**  
Tecfidera may decrease lymphocyte counts. In clinical trials there was a 30% reduction during the first year which then remained stable. Four weeks after stopping Tecfidera, mean lymphocyte counts increased but not to baseline. 4% of Tecfidera patients and 1% of placebo patients had lymphocyte counts < 45 x 10<sup>9</sup>/L. Tecfidera has not been studied in patients with pre-existing low lymphocyte counts. The incidence of infections and serious infections was similar in patients treated with Tecfidera or placebo. Consider withholding treatment in patients with serious infections until resolved. A complete blood count is recommended within 4 months before initiating treatment, annually, and as clinically indicated.

Tecfidera may cause flushing in a variety of settings, including during treatment. 40% of patients taking Tecfidera reported flushing which was mostly mild to moderate in severity. The percentage of patients discontinued Tecfidera for flushing and 4% had serious flushing events that led to hospitalization. Taking Tecfidera with food may reduce flushing.

Tecfidera may cause gastrointestinal (GI) events, e.g., nausea, vomiting, diarrhea, abdominal pain, and bloating. Four percent of Tecfidera patients and 4% placebo patients discontinued due to GI events. The incidence of serious GI events was 1%. The most common adverse reactions associated with Tecfidera versus placebo are flushing (40% vs 4%), and GI events: abdominal pain (10% vs 10%), diarrhea (10% vs 11%), nausea (12% vs 10%).

Flushing in pregnant women and patients who have been reported. A treatment discontinuation rate of 10% was seen during the 6 to 12 months. Tecfidera should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Encourage patients who become pregnant while taking Tecfidera to enroll in the Tecfidera pregnancy registry by calling 1-800-456-2222.

For additional important safety information, please see Brief Summary of Full Prescribing Information on the following page.

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**Tecfidera launch materials stressed first-line use. Above: a journal ad**

report "reaffirms [the] company's initial assessment...that the death is unlikely related to Tecfidera," a spokesperson says.

Glasser says the keys to the launch strategy included product messaging and positioning: "We decided to message heavily for first-line use."

The firm's commercial footprint helped. Biogen Idec sells Avonex, the top interferon product, and the infused med Tysabri, so its sales force had a solid rep. But, "we didn't take that for granted. We really treated this as if

it was a new product," says Glasser.

She also credits a cross-functional team, which extended to medical-regulatory and market access. Plus, the med was priced smartly at \$55K a year — \$10,000 above Aubagio's annual price but well beneath Gilenya's.

After a week, Tecfidera reached a prescription level it took Gilenya about three months to hit. Early consensus 2013 estimates were for around \$300 million in US sales. In the third quarter alone, the drug had \$280 million in sales. In its first six months, it captured more new 'scripts than Gilenya and Aubagio combined, and it's been prescribed by 5,000 physicians.

When asked whether Tecfidera will do something like Gilenya's sassy "Take This, MS!" consumer campaign, or Aubagio's "List" campaign, she says it's premature to comment on the biotech's exact plans for DTC advertising.

Challenges include the loss of patent protection, expected in June, for Teva's market-leading injectable MS drug Copaxone, which may test the stickiness of Tecfidera prescriptions.

Still, Glasser says. "Tecfidera's launch puts us in a good position... but it will require sustained commercial efforts because we're ambitious about what this product should do."

— Marc Iskowitz

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# maestros

## AGENCY ROSTER

**AOR**  
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**MEDIA/  
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Razorfish  
Healthware

**STRATEGY**  
Return on Focus

**PR**  
GCI Health



L-R: Deb Glasser,  
assoc. dir., US  
Tecfidera mkt.;  
Constantine  
Velentzas, sr.  
prod. mgr., US  
Tecfidera mkt.;  
Art Enk, sr. dir.  
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Biogen Idec