Sept. 9, 2016
**Exondys gets FDA nod**
Sarepta’s eteplirsen, now known as Exondys, is conditionally approved to treat people whose Duchenne muscular dystrophy is caused by a mutation in exon 51. Later that day, the biotech firm says the drug will cost on average $300,000 per year.

Oct. 4, 2016
**Combination therapy sought**
Sarepta pays $40 million for the European rights to Summit Therapeutics’ utrophin modulators. The deal follows a smaller agreement to conduct preclinical studies of exon-skipping drugs in combination with Catabasis Pharmaceuticals’ NF-κB inhibitors.

Oct. 7, 2016
**Anthem controversy**
Anthem, one of the country’s largest insurers, says it will not cover Exondys. The company later reportedly agrees to cover the drug for a child whose family challenged the policy.

**Sarepta’s golden ticket**
FDA issues Sarepta a priority review voucher, which can be used to shorten the agency’s review of a new drug application by four months. PRVs are transferrable and have been sold for as much as $350 million.

Oct. 19, 2016
**FDA hubbub**
John Jenkins, director of FDA’s Office of New Drugs, tells the audience at rare disease summit that the path taken by Sarepta is “not a good model for other development programs.” He devotes several slides to its deficiencies.

Nov. 4, 2016
**Surrogate endpoints questioned**
More documents related to FDA’s review of eteplirsen are released, including emails between officials debating the reliability of the limited data on the drug.

“The drug has provided a worrisome model for the next generation of molecularly targeted therapies: demonstrate a slight difference in a laboratory test, activate the patient community, win approval, and charge high prices, while relying on limited regulatory follow-up.” — Aaron Kesselheim and Jerry Avon of Harvard Medical School

Sources: companies, FDA, JAMA