## The future is now: Gene therapy to take flight in Europe

After many years of crushed expectations, gene therapy could be close to a victory: a regulatory approval.

The European Medicines Agency has recommended approval of a <u>gene therapy</u> to treat a rare genetic disease, called lipoprotein lipase deficiency, which prevents people from digesting fat. The drug, called Glybera, created by Dutch-based company uniQure, had previously been rejected by the EMA three times.

This recommendation still requires approval by the European Commission, which is expected within three months. Many anticipate that the drug will be approved, due to the fact that the EC generally follows advice from the EMA.

If Glybera is indeed approved, it will be the first commercial gene therapy to win regulatory approval in the West. The only additional gene therapy drug commercially available is Gendicine, which is used in China to treat cancer.

It is still unclear whether or not uniQure will apply for FDA approval for US marketing.

## **Additional Resources:**

- Gene therapy for lipoprotein lipase deficiency close to approval in Europe, Global Post
- First gene therapy close to approval, Web MD
- EC set to approve first drug based on gene therapy, The Economic Times