Quantum Leap: How Do Drugs Go From Research to Retail?

Benlysta is close to becoming the first new med the FDA has approved in 50 years to fight lupus. Just how does a new drug get fast-tracked onto pharmacy shelves? Real Health spoke with Jerry Parrott, of the Human Genome Sciences, one of the companies researching Benlysta, about the FDA process and this potential lupus breakthrough.

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“The most misunderstood thing about lupus is that a lot more people are affected by it than we know,” says Tomiko Fraser Hines, a well-known African-American model whose younger sister, Shneequa, contracted the disease in 1997. (Her story appeared in *Real Health*’s 2008 winter issue.)

Although Fraser Hines’s sister contracted lupus when she was 20, the disease can occur at any age. In addition, even though anyone can contract lupus, the condition is more likely to develop in African-American women and other women of color, particularly those of childbearing years (ages 15 to 44).

Essentially, lupus is an autoimmune disease, which means the body can’t tell the difference between its own cells and foreign invaders. As a result, the body attacks itself. The disease is non-contagious and chronic, and it can harm any part of the body, especially the skin, joints, blood and organs. Doctors aren’t sure what causes lupus, but some feel it is genetically transmitted.

For Shneequa, lupus attacked her in a particularly devastating way. She suffered permanent brain damage, which also caused an irreversible speech disability and mobility impairment. These serious conditions required that her family put her in a nursing facility for around-the-clock care.

After the condition triggered a seizure in October 2008, however, Fraser Hines’s sister deteriorated rapidly. She died in March 2009.

In individuals, lupus varies from being mild to life-threatening. But the majority of people can lead full lives if they receive good medical care and effective meds.

Which is why the lupus community is excited about the drug Benlysta. Currently being researched by Human Genome Sciences and GlaxoSmithKline, the med is poised to be the first drug the Food

and Drug Administration (FDA) has approved to fight lupus in 50 years.

To get an FDA approval, a drug must successfully navigate a rigorous process. Jerry Parrott, vice president of corporate communications and public policy for Human Genome Sciences, offers a window into this process by explaining Benlysta's backstory.

To qualify for FDA drug approval consideration, pharmaceutical companies must extensively analyze the medication. Parrott says the Benlysta studies included 1,700 people, the largest clinical trials ever conducted on lupus patients.

Before a drug can be tested on people, however, companies usually test the drug in labs and on animals to determine how it works and what its safety and effectiveness might be in humans.

Next, the company conducts a series of tests on people, called clinical trials, to evaluate the drug's safety and health benefits when used to treat a disease.

During the clinical trials, scientists must also evaluate a drug's side effects. "It's always important," Parrott says, "but especially so for an autoimmune disease like lupus. People with autoimmune diseases are prone to infection, so you have to be very alert to the possibility of those patients' immune systems being further compromised.

"Those patients' standard of care already involve the use of heavyweight medication, such as high-dose steroids, that have very serious side effects," Parrott continues. "When you add a new treatment [drug], it's very important that the safety profile be excellent."

Besides Benlysta's positive show of safety, researchers also noted the drug was well-tolerated and it significantly reduced the disease's activity, Parrott adds.

Typically, pharmaceutical companies organize clinical trials in stages called phases. Sometimes, phases may consist of more than one study. For example, when Benlysta reached the Phase III stage of its clinical trials, researchers conducted two studies for that period.

In addition to looking for side effects, researchers carefully note any adverse effects a drug may have.

"Sometimes, you can have an adverse effect and not know exactly what causes it," Parrott explains. "Then investigators have to make a judgment about whether or not the adverse effect is drug related."

During its Phase III stage, a drug undergoes exhaustive analysis. If the analysis yields positive results, the pharmaceutical company prepares and submits what's called a biologics license application to the FDA and regulatory authorities in Europe and other regions to get permission to market the drug.

The application process alone can take a few months, Parrott says.

Currently, Benlysta is in this late stage of the quest to receive FDA approval. But there's also a chance that the drug might get a priority review.

"You never know until the FDA tells you there's a likelihood that this drug may receive priority review," Parrott explains. "If that's the case, that's essentially a six-month process. [If approved] we would expect the drug on the market and available to patients by the end of next year."

What are the chances of Benlysta receiving a priority review? "It's based on a combination of patient need and a confirmation of the drug's safety from the late-stage trial observations," Parrott says.

Human Genome Sciences plans to submit marketing applications for Benlysta in the United States and Europe in the second quarter of 2010. It's hoped that the drug will receive FDA approval and then be launched in the United States by the end of this year.

But should Human Genome Science receive the OK to market Benlysta, it must go through one last step in the clinical trial procedure: the Phase IV stage. During this period, more studies are done after companies market the drug or treatment. The purpose is to gather information on the drug's effect in various populations and document any side effects associated with its long-term use.

Although it's too late for Tomiko Fraser Hines's sister, Benlysta does represent new hope for the nearly 1.5 million Americans who have lupus and those who are affected by the condition.

But the drug is also just as important to the scientists and pharmaceutical companies on a mission to find a new treatment for lupus.

As Parrott says: "It's an extremely gratifying feeling for the people who have been working on this for so long."

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