FDA approves generic blood thinner

July 26 2010, By Andrew Zajac

In a closely watched decision, the Food and Drug Administration on Friday approved an application by German drug-maker Sandoz and Momenta Pharmaceuticals of Cambridge, Mass, to make the first generic version of the widely used blood thinner Lovenox.

The approval positions Momenta and Sandoz to offer a cheaper but still lucrative alternative to Lovenox, which had sales of $4.5 billion in 2009, making it the 15th best selling drug in the world.

In its decision, the FDA also rejected an argument by Lovenox's maker, Sanofi-Avenis, that its drug, which is made from sugar molecules found in heparin, a substance derived from pig intestines, is too complex to be copied with precision by makers of generic versions of the medication.

The Sandoz/Momenta team had been in a bitter, five-year battle with Amphastar Pharmaceuticals, of Rancho Cucamonga, Calif., to win the FDA's nod to make the drug, which goes by the generic name enoxaparin.

Amphastar last year accused Janet Woodcock, the FDA's top drug official, of a conflict of interest involving her past associations with Momenta scientists. The complaint was dismissed by the Department of Health and Human Services Inspector General.

"The approval of M-enoxaparin marks a key milestone for Momenta and we are extremely pleased," Momenta CEO Craig Wheeler said in a statement.

Shares of Momenta, which supplied the technology in its partnership, zoomed to $21.70, up $9.77, an increase of more than 80 percent. Shares of Sandoz' parent, Swiss pharma conglomerate Novartis, closed down 35 cents at $49.21.

Sanofi shares lost $1.29, closing at $29.35.

The contours of the FDA announcement could bode well for Momenta, according to analyst Bret Holley, of Oppenheimer Co.

The Momenta's partnership agreement with Sandoz is much more generous if their application is the only one approved, Holley said.

Typically, Holley said, when the FDA rejects a petition by a drug's original maker as it did with Sanofi Avenis, it announces all the generic approvals at the same time, suggesting that Sandoz/Momenta might be the only application slated for approval.

Holley also said that the painstaking review of the Sanofi Avenis request, conveyed in a 45-page letter, suggests that the FDA will move cautiously when considering generic versions of drugs derived from natural substances.

"I don't believe that they're going to be approving applications (for biogenerics) willy-nilly," he said.

Amphastar attorney Jason Shandell declined to specify his company's next move, but hinted that it was not ready to throw in the towel.

"As the first filer, we're obviously very disappointed and we will do everything we can to allow the system to correct such a mistake," Shandell said. Amphastar applied to make enoxaparin in 2003, two years earlier than Sandoz/Momenta.

The FDA still could approve Amphastar's application, but the company would not have first-mover advantage and would be competing against the global distribution capabilities of Sandoz.

Amphastar's allegation of a conflict of interest involving Woodcock centered on her partnering with Momenta scientists in investigating the heparin crisis in early 2008 in which contaminated lots of the drug from China sickened, and in some cases killed, patients.

Amphastar argued that the collaboration and earlier contacts between Woodcock and Momenta scientists inclined the FDA to favor Momenta.

Momenta has said that there is nothing inappropriate in its relationship with regulators.