

# BIOCENTURY EXTRA

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BioCentury Extra for Tuesday, August 29, 2006

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## TUESDAY'S TOP STORY

### FDA panel backs Adeza's Gestiva

FDA's Reproductive Health Drugs Advisory Committee voted 12-9 to recommend approval of **ADZA's** NDA for Gestiva to prevent preterm birth in women with a history of preterm delivery. The committee said that the clinical data submitted in the NDA was adequate for approval. The panel also recommended that the company provide post-marketing data that could involve additional clinical trials.

The NDA, which was submitted under section 505(b)(2) of the Food, Drug and Cosmetic Act, is under Priority Review with an Oct. 20 PDUFA date. Gestiva is a long-acting form of a naturally occurring progesterone, 17 alpha-hydroxyprogesterone caproate (17P). ADZA was up \$0.61 to \$15.91 on Tuesday.

## CLINICAL NEWS

### ViroPharma up on HCV data

**VPHM** gained \$1.44 (13%) to \$12.61 on Tuesday after reporting preliminary Phase Ib data for its HCV-796 plus pegylated interferon to treat chronic HCV infection in treatment-naive patients. Data from the study showed the combination produced a mean viral reduction of 3.3-3.5 log<sub>10</sub> at day 14 compared with 1.7 log<sub>10</sub> for patients receiving pegylated interferon plus placebo.

The primary endpoint of the trial is safety. Although the safety data remain blinded, the company said that tolerability was consistent with that expected from pegylated interferon. Full data will be presented in the second quarter of 2007.

VPHM is developing HCV-796, a non-nucleoside viral polymerase inhibitor, under a deal with Wyeth (**WYE**). The companies expect to start a Phase II trial of HCV-796 next quarter.

### OrthoLogic stops Chrysalin Phase IIb

**OLGC** discontinued a Phase IIb trial of Chrysalin (TP508) to treat unstable distal radius fractures after interim data showed that the compound did not show significant benefit in the primary and secondary endpoints. The primary endpoint was time to removal of all rigid immobilization for fracture, while secondary endpoints included time to clinical healing, time to

### BioCentury 100™ & BioCentury London Indicators

▲100™: 1549.23	+ 14.09	+0.9%
Advance/Decline: 65/33		
▼London: 518.92	- 1.96	-0.4%
▲ DJIA: 11369.94	+ 17.93	+0.2%
▲ Nasdaq: 2172.3	+ 11.60	+0.5%
▲ S&P 500: 1304.28	+ 2.50	+0.2%
▲ ^DRG: 349.97	+ 2.21	+0.6%
▲ FTSE 350: 3050.2	+ 6.10	+0.2%
▲ ^IXK: 940.52	+ 3.21	+0.3%

### BioCentury 100™ Top 5 Advancers

ViroPharma Inc.	+\$1.44	+12.9%
CV Therapeutics Inc.	+\$0.86	+ 7.8%
Exelixis Inc.	+\$0.63	+ 7.5%
Pharmion Corp.	+\$1.15	+ 6.7%
Alexion Pharmaceuticals Inc.	+\$2.23	+ 6.1%

### BioCentury 100™ Top 5 Decliners

ZymoGenetics Inc.	-\$1.35	- 6.4%
Accelrys Inc.	-\$0.15	- 2.7%
Crucell N.V.	-\$0.54	- 2.5%
MedImmune Inc.	-\$0.58	- 2.0%
Maxygen Inc.	-\$0.15	- 1.9%

### Upcoming Event

THE 13th ANNIVERSARY  
OF  
**NEWSMAKERS**  
IN THE BIOTECH INDUSTRY

A COLLABORATIVE GATHERING  
OF THE CORPORATE AND  
INVESTMENT COMMUNITIES

Thursday  
September 7, 2006  
Millennium Broadway  
Hotel & Conference Center  
New York City

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