Industry Spotlight

New Drug Performs in Chronic Kidney Disease Clinical Trial

La Jolla Pharmaceutical Company announced on March 10 that its lead experimental drug, which treats chronic kidney disease, met its primary goal of improving kidney function as measured by blood filtering through the kidneys.

The results from the phase 2a study lent the company's shares a 40 percent bump in trading upon the announcement, which reported results with two tested doses of the drug, known now as GCS-100.

The lower dose was more favorable than the higher. The lower amount of drug showed an increase in the rate of blood filtering, whereas the higher dose did not. The lower dose also reduced the levels of galectin-3, a protein associated with tissue scarring, which causes organ damage.

The higher dose did not show a statistically significant increase in either the rate of blood filtering or the decrease of galectin-3 levels in comparison with placebo. The researchers speculated that a higher dose of the drug might stop the production of galectin-3 so much and so effectively that the body might start producing the protein again, in a feedback loop effect.

The doses were well tolerated, with no adverse effects in the lower-dose group; side effects in the higher-dose group were not related to the drug, the company reported.

Reuters wrote that analysts were bullish on the results. "Even with a modest penetration, we estimate the drug could have more than $2 billion in peak sales in 2024, and that is a conservative estimate," said Ling Wang of Chardan Capital Markets.

Before the company announced the results, Wedbush analysis Liana Moussatos gave an "outperform rating," StreetInsider reported.

"GCS-100 is the lead drug candidate which reduces elevated galectin-3 associated with chronic kidney disease and nonalcoholic steatohepatitis (NASH)—both large market opportunities for which the standard-of-care can cause life-threatening side effects and/or has no approved therapies," Moussatos said.

DaVita Settles After Federal Investigation

DaVita, the second largest provider of dialysis services in the United States, has agreed to a framework for "a global resolution with government officials for both the 2010 and the 2011 U.S. Attorney Physician Relationship Investigations," the company shared in its most recent financial report.

The company announced that the settlement will include the payment of approximately $389 million, an amount previously announced and put into reserve.

"We have agreed to unwind a limited subset of joint ventures that were created through partial divestiture to nephrologists, and agreed not to enter into this type of partial divestiture joint venture with nephrologists in the future," the statement read.

DaVita HealthCare Partners said it would pay to settle criminal and civil antikickback investigations. Its joint ventures with kidney doctors involved 28 dialysis clinics.

The *Denver Post* reported that Kent Thiry, DaVita's chief executive officer, said the exact settlement is being finalized.

The *Post* noted that Garry Menzel, DaVita's chief financial officer, said the company "most likely" will buy out or sell 11 joint ventures it reached with kidney doctors at "fair market value."

Overall, DaVita had a good year in 2013 and showed an improvement over year 2012 income earnings. Income for the quarter ended December 31, 2013, and the adjusted income for the year ended December 31, 2013, from continuing operations attributable to DaVita HealthCare Partners, Inc., were $212.3 million and $817.6 million, respectively.

Adjusted income from continuing operations attributable to DaVita HealthCare Partners, Inc., for the quarter and year ended December 31, 2012, was $173.8 million and $612.6 million, and that adjusted income excluded the loss contingency reserve and a different adjustment.

New Rules Proposed for Use of Off-Label Drugs and Devices

The U.S. Food and Drug Administration (FDA) is revising, for the first time since 2009, its draft guidance on how to present and publish information about off-label use of a drug or device.

The FDA is recommending practices for drug or medical device manufacturers and their representatives to follow when distributing to health care professionals or health care entities "scientific and medical publications that discuss unapproved new uses of approved drugs or approved or cleared medical devices," the FDA said in an advance copy of its Federal Register notice.

Bloomberg News reported that the guidance is that generally such publications are required to appear in journals, scientific or medical reference texts, and clinical practice guidelines. The draft guidance contains separate but related recommendations for those three types of publications.

The draft guidance recommends that the information have a "prominently displayed and permanently affixed statement that some of the uses for the drugs and/or devices being distributed might not have FDA approval or clearance."

According to MedPage Today, a medical news website for health care professionals, the new rules would mean that information about off-label use must

- be peer reviewed
- be published by an organization that has an editorial board that includes an independent expert
- be distributed with approved labeling
- be distributed separately from promotional information
- include opposing views—when available—regarding the unapproved use
- present a reprint that is unabridged

The draft guidance on off-label use is open for public comment until May 2, 2014. Submit electronic comments to http://www.regulations.gov.

Written comments may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.