NEWS RELEASE

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For Immediate Release

LOCAL BIOTECH FIRM FINED $250,000 FOR CONCEALING TOXIC NATURE OF PRODUCT FROM THE FDA

NEWS RELEASE SUMMARY – February 21, 2014

San Diego biomedical device manufacturer Valor Medical, Inc. was fined $250,000 today by U.S. District Judge Dana M. Sabraw for intentionally withholding unfavorable test results from the Food and Drug Administration about products under development for the treatment of aneurysms.

Valor had been seeking FDA approval to proceed with clinical trials of the devices in question, including one intended for use in blood vessels in the brain, known as Neucrylate AN, and one intended for use in blood vessels near the heart, called Neucrylate AVM. But the actual preclinical test results would have cast doubt on the safety of Neucrylate, so the company concealed the results.

No Americans were harmed because the FDA never permitted clinical trials to proceed in the United States. However, one death and two strokes occurred as part of clinical trials of the product in Europe, where the European authorities were also unaware of the undisclosed test reports.

Former Valor CEO and current member of the Board of Directors H. Clark Adams and Valor Regulatory and Clinical Affairs Manager Cathy Bacquet pleaded guilty to misdemeanors, and Valor founder Dr. Charles Kerber and Chief Scientist Peter Friedman entered into Deferred Prosecution Agreements, for their roles in the matter.

Because Neucrylate is considered be a Class III medical device under the Food, Drug and Cosmetic Act ("FDCA"), premarket approval from the FDA is required before it can be sold in the United States. In order to perform clinical trials on humans to obtain the data needed to support an application for premarket approval, Valor needed to obtain an investigational device exemption ("IDE") from the FDA. The regulations relating to investigational device exemptions require the applicant to submit "reports of all prior clinical, animal and laboratory testing of the device."

As the device is intended to be permanently implanted in the body, biocompatibility is very important. The FDA evaluates the biocompatibility of medical devices pursuant to international standards, which require a series of at least three tests. Two of the three tests typically performed to satisfy these requirements are the mouse lymphoma assay (MLA) and the chromosomal assay (CAA) tests.

According to sentencing documents filed with the court, Valor sent samples of Neucrylate to a laboratory to perform the CAA and MLA tests in early 2007. Shortly thereafter, the lab reported to Alan Donald, a consultant hired by Valor, that all the chromosomes in the CAA test had been destroyed by initial contact with the Neucrylate, indicating toxicity.

The lab asked if Valor wanted the lab to dilute the samples of Neucrylate and try the test again, which is the standard protocol. Donald requested that no further testing be performed. The final report, dated April 25, 2007, indicated that "no chromosomes were present to be scored." While the destruction of all chromosomes indicated that the Neucrylate was cytotoxic, the official conclusion to the report stated that no conclusion could be drawn from the testing because the testing had not been completed pursuant to the testing protocol.[1]

At about the same time, the laboratory sent an email to Friedman, with the preliminary results of the MLA test attached, advising that "all testing has been completed and the test article is considered to be mutagenic." Friedman forwarded the email, with the attached preliminary results, to Donald, Adams, and Kerber later that same day. Adams replied to all, saying "Let's huddle and determine how we overcome this obstacle. I have confidence that we can find an answer."

Neither the CAA test results nor the MLA test results were ever provided to the FDA by Valor, which filed two separate investigational device exemption applications and responded to several additional

1 The lab's internal Quality Event Details Form noted that the samples for the CAA test were "cytotoxic," and the results were valid, but the sponsor was "choosing to cancel the study rather than perform dilutions" so a "full conclusion as to the genotoxicity of the sample will not be made."

requests for information from the FDA (virtually all of which specifically requested that the CAA and/or MLA tests be performed).

The FDA rejected all of Valor's IDEs for Neucrylate.

After a December 2010 inspection of Valor uncovered the CAA test, the FDA sent a warning letter to Adams at Valor. The letter referenced the failure to disclose the CAA testing as a violation of the regulations requiring an applicant to submit all preclinical testing to the FDA.

When responding to the FDA on behalf of Valor, Defendant Bacquet claimed that Valor "inadvertently" left out the CAA and MLA tests in the application for the IDE. Valor blamed this "unintentional violation" on Valor's reliance on the work of consultant Alan Donald, who had separated from the company nearly a year before that IDE was filed. The letter falsely stated that "Prior to February 10, 2011, the existence of this report [the MLA] was not known to VM management or Quality/Regulatory staff." This statement was contradicted by a series of emails between Friedman, Kerber, Adams, and Donald from the time period when the MLA results were received by Valor in 2007, as well as by presence of the MLA report on the computers of Friedman and Bacquet.

The American people depend on the FDA to determine that there is sufficient scientific basis to believe that a proffered medical device is safe and effective before permitting clinical trials on human beings. The FDA, in turn, depends on the full and truthful disclosure of all pre-clinical testing by device manufacturers to make an educated determination. When information is withheld from the FDA, as in the instant case, the decision-making process is corrupted.

DEFENDANT **Criminal Case No. 14cr0196-DMS**

Valor Medical, Inc.
San Diego, California Date of Incorporation: 2007

SUMMARY OF CHARGES

Failure to Provide Required Information, a felony, in violation of Title 21, United States Code, Section 331(q)(1)(B) and 333(a)(2)
Maximum Penalty for a corporation: 5 years of probation, a $500,000 fine, $400 special assessment

INVESTIGATING AGENCY

U.S Food and Drug Administration, Office of Criminal Investigations