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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

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**Novartis Vaccines & Diagnostics to Pay More Than \$72 Million to Resolve False Claims Act Allegations Concerning TOBI**

WASHINGTON – Novartis Vaccines & Diagnostics Inc. and Novartis Pharmaceuticals Corporation have agreed to pay \$72.5 million to resolve civil False Claims Act allegations arising from the marketing of the cystic fibrosis drug TOBI, the Justice Department announced today. The settlement resolves allegations that, between Jan. 1, 2001 and July 31, 2006, Novartis and its predecessor, Chiron Corporation, caused false claims to be submitted to federal health care programs for certain off-label uses of the drug.

The Food and Drug Administration (FDA) approved TOBI, an inhaled antibiotic, for the treatment of certain cystic fibrosis patients. The United States alleges that Chiron, and then Novartis, marketed TOBI for unapproved uses, such as diseases other than cystic fibrosis, and for cystic fibrosis patients who did not meet the parameters of the FDA-approved indication and for which TOBI was not a medically accepted use. The government alleges that this conduct caused the submission of false claims to federal health care programs.

"Pharmaceutical companies must not promote their drugs for uses that have not been proven to be safe and effective," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "We are committed to pursuing False Claims Act violations and recovering taxpayer dollars lost to off-label marketing."

"This office is committed to safeguarding the federal health care programs against false claims caused by off-label marketing and other types of illegal conduct," said Joseph Russoniello, U.S. Attorney for the Northern District of California.

Under the agreement announced today, the proceeds from the settlement will be divided between the federal government and various states, with the United States receiving \$43.5 million to resolve the federal claims, and the states receiving \$29 million to settle their respective claims.

"The Defense Criminal Investigative Service (DCIS) is thoroughly committed to pursue any and all allegations of fraud that drain precious resources from America's war fighters," said Richard W. Gwin, Special Agent in Charge of the DCIS Western Field Office. "This particular fraud was directly related to the healthcare of our brave soldiers, sailors, airmen, marines and their families throughout the world. The settlement with Novartis was only made possible by the hard work of the prosecutors from the Department of Justice, agents from the DCIS and all the other joint investigative agencies."

This settlement resolves a lawsuit brought by three former Chiron employees – Robert Lalley, Courtney Davis and William Manos – under the *qui tam* or whistleblower provisions of the False Claims Act, which permit private individuals known as relators to bring a lawsuit on behalf of the United States and to share in any recovery. The relators will receive \$7.825 million of the federal share of the settlement announced today.

This settlement is part of the government's emphasis on combating health care fraud. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover approximately \$2.3 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department's total recoveries in False Claims Act cases since January 2009 have topped \$3 billion.

The settlement was the result of a coordinated effort among the Commercial Litigation Branch of the

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Civil Division

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