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TRANS1, INC. TO PAY U.S. \$6 MILLION TO SETTLE
FALSE CLAIMS ACT ALLEGATIONS

Baltimore, Maryland - Medical device manufacturer TranS1, Inc., now known as Baxano Surgical, Inc., has agreed to pay the United States \$6 million to resolve allegations under the civil False Claims Act that the company caused health care providers to submit false claims to Medicare and other federal health care programs for minimally-invasive spine surgeries.

The settlement was announced today by United States Attorney for the District of Maryland Rod J. Rosenstein; Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division; Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services; Special Agent in Charge Robert Craig of the Defense Criminal Investigative Service - Mid-Atlantic Field Office; and Special Agent in Charge Drew Grimm, Office of Personnel Management, Office of Inspector General.

This settlement resolves allegations that TranS1 knowingly caused health care providers to submit claims with incorrect diagnosis or procedure codes for certain minimally-invasive spine fusion surgeries in which physicians used TranS1's AxiaLIF System™, a device developed as an alternative to invasive spine fusion surgeries. The United States further alleges that TranS1 improperly counseled physicians and hospitals to bill for the AxiaLIF System™ by using incorrect and inaccurate codes intended for more invasive spine fusion surgeries. As a result, the United States contends that health care providers received greater reimbursement than they were entitled to for performing the minimally-invasive AxiaLIF procedures.

"A medical device manufacturer violates the law when it advises physicians and hospitals to report the wrong codes to federal health insurance programs in order to increase reimbursement rates," said Rod J. Rosenstein, United States Attorney for the District of Maryland. "Health care providers are required to bill federal health care programs truthfully for the work they perform."

"The Justice Department is committed to ensuring that medical device manufacturers follow the law when providing devices to beneficiaries

of federal health care programs," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "It is critical that health care providers bill federal health care programs accurately and honestly for the work they perform, and it is imperative that they base their selection of medical devices on the best interests of their patients, not on whether a device manufacturer is paying them for promotional speaking or consulting."

The settlement also resolves allegations that TranS1 knowingly paid illegal remuneration to certain physicians for participating in speaker programs and consultant meetings intended to induce them to use TranS1 products, in violation of the Federal Anti-Kickback Statute, and thereby caused false claims to be submitted to federal health care programs. The Anti-Kickback Statute, prohibits offering or paying remuneration to induce referrals of items or services covered by federally-funded programs and is intended to ensure that a physician's medical judgments are not compromised by improper financial incentives and are based solely on the best interests of the patient.

Finally, the settlement resolves the United States' allegations that TranS1 promoted the sale of its AxiaLIF System™ for uses that were not approved or cleared by the U.S. Food and Drug Administration, including in certain procedures to treat complex spine deformity, which were not covered by federal health care programs.

As part of the settlement, TranS1 has agreed to enter into a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect similar conduct.

"Using kickbacks to encourage health providers to make false payment claims will not be tolerated," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "TranS1's agreement to now comply with government health laws is encouraging."

The civil settlement resolves a lawsuit filed under the whistleblower provision of the False Claims Act, which permits private parties to file suit on behalf of the United States for false claims and obtain a portion of the government's recovery. The civil lawsuit was filed in the District of Maryland and is captioned United States ex rel. Kevin Ryan v. TranS1, Inc. As part of today's resolution, Mr. Ryan will receive \$1,020,000 from the settlement.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was

announced by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than \$10.7 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 are over \$14.5 billion.

The settlement was a result of an investigation by the U.S. Attorney's Office for the District of Maryland, the Justice Department's Civil Division, the Inspector General of Department of Health and Human Services, the Department of Defense Criminal Investigative Services and the Inspector General for the Office of Personnel Management. The case was handled by Assistant U.S. Attorneys Thomas Barnard and Thomas Corcoran and Trial Attorney Colin Huntley of the Justice Department Civil Division.
