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Investor News

Bayer and Nuvelo announce Phase 3 trials of alfimeprase in Patients with acute peripheral arterial occlusion and catheter occlusion did not meet primary endpoint

Leverkusen, Germany / San Carlos, Calif., U.S., December 11, 2006 – Bayer HealthCare (BHC) and Nuvelo Inc. (Nasdaq: NUVO) today announced top-line data demonstrating that the Phase 3 clinical trial of alfimeprase in acute peripheral arterial occlusion (PAO), known as NAPA-2 (Novel Arterial Perfusion with Alfimeprase-2), did not meet its primary endpoint of avoidance of open vascular surgery within 30 days of treatment. The companies also announced that the Phase 3 trial in catheter occlusion (CO), known as SONOMA-2 (Speedy Opening of Non-functional and Occluded catheters with Mini-dose Alfimeprase-2), did not meet the endpoint of restoration of function at 15 minutes. These trials did not meet key secondary endpoints. In addition, the companies announced that they have temporarily suspended enrollment in the ongoing Phase 3 trials, NAPA-3 and SONOMA-3, until further analyses and discussions with outside experts and regulatory agencies are completed.

These data will be submitted for presentation at the next appropriate medical meetings.

"These outcomes are disappointing particularly for patients with acute PAO, who have few treatment options," said Dr. Ted W. Love, chairman and chief executive officer of Nuvelo. "We and our partner Bayer will conduct further analyses and have discussions with the Data Safety and Monitoring Board members, outside experts and regulatory authorities to determine how to proceed with the development of alfimeprase, including the possibility of alternative dosing and delivery."

About NAPA-2

NAPA-2 was a randomized, double-blind study that compared the efficacy and safety of 0.3 mg/kg of alfimeprase versus placebo in 300 patients worldwide. The study's primary endpoint was avoidance of open vascular surgery within 30 days of treatment. A variety of secondary endpoints were also evaluated, including restoration of arterial blood flow, safety endpoints such as the incidence of bleeding, and pharmacoeconomic endpoints such as length of hospital and intensive care unit stay.

About SONOMA-2

SONOMA-2 was a randomized, double-blind trial comparing the efficacy and safety of 3 mg of alfimeprase with placebo in a 2:1 ratio in 303 patients with occluded central venous catheters. The study's primary endpoint was restoration of function to the occluded catheter in 15 minutes.

About the Collaboration

Nuvelo and Bayer HealthCare have a global collaboration for the development and commercialization of alfimeprase. Under the terms of the agreement, Bayer will commercialize alfimeprase in all territories outside the United States and will pay Nuvelo tiered royalties. Nuvelo retains commercialization rights in the United States and will remain the lead for the design and conduct of the global development programs.

Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the health care and medical products industry based in Leverkusen/Germany. In 2005, the Bayer HealthCare subgroup generated sales amounting to some 9.4 billion Euro. Bayer HealthCare employed 33.800 people worldwide in 2005.

The company combines the global activities of the divisions Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Since January 1, 2006, the new Pharmaceutical Division consists of the former Biological Products and Pharmaceutical Division and now comprises three business units: Hematology/Cardiology, Oncology and Primary Care.

Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

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Forward-looking statements

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