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## **FDA CLEARS GLYCOMARK TEST FOR PEOPLE WITH DIABETES**

### **GlycoMark™ Monitors Intermediate Glycemic Control**

(New York, NY) – November 6, 2003 - Tomen America Inc. and Nippon Kayaku Co. Ltd. today announced that the U.S. Food and Drug Administration (FDA) has granted marketing clearance for the GlycoMark™ test. This blood test is cleared for the intermediate term monitoring of glycemic control (measurement of overall glucose control over time) in people with diabetes. Data from a prospective clinical study conducted at Washington University (St. Louis, Missouri) is being presented today at the Diabetes Technology Meeting in San Francisco, California.

The GlycoMark™ test measures the level of 1,5-anhydroglucitol (1,5-AG) in human blood. 1,5-AG responds rapidly to increasing glucose levels and reflects average glucose levels over a period of a few days to 2 weeks. This may allow patients to seek medical intervention in a timely manner such as when starting or changing therapy, empowering patients to achieve and maintain control of their disease.

According to the American Diabetes Association, monitoring of glycemic status is a cornerstone of diabetes care. Glycemic tests such as hemoglobin A1c, fructosamine, and now GlycoMark™, provide measures of overall glucose control and are important in maintaining near-normal glucose levels. As an intermediate-term monitoring test of glycemic control, GlycoMark™ is an additional tool for the physician to measure more recent glycemic status to monitor diabetes therapy timely and effectively.

"GlycoMark™ is an important new test which physicians may use to monitor glycemic control," said Dr. Steve Edelman, Professor of Medicine at the University of California, San Diego. "Fructosamine has been somewhat disappointing as a measure of short-term glycemic control due to its inherent variability, and the availability of GlycoMark™ would certainly be a welcome addition to the tools available to monitor glycemia."

"Receiving FDA marketing clearance for the GlycoMark™ test in the United States is an important milestone for Tomen America and Nippon Kayaku. There is significant market potential for an accurate, consistent test that

monitors intermediate glycemic control in patients with diabetes," said Eric Button, president of BioEmerge Partners, a life science venture development firm based in Winston-Salem, NC.

Current research is focused on the ability of GlycoMark™ to measure postprandial hyperglycemia (after-meal glucose levels) in diabetic patients. Control of postprandial hyperglycemia is the subject of intensive pharmaceutical/academic research and development.