

# News Release

For Immediate Release

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## **BioWa and Medarex Announce Allowance of Investigational New Drug Application for Second-Generation Anti-CD30 Antibody (MDX-1401) Enhanced Using Potelligent™ Technology**

**Princeton, N.J.; January 9, 2007** - BioWa, Inc. and Medarex, Inc. (NASDAQ: MEDX) announced today the allowance of an investigational new drug application (IND) filed with the U.S. Food & Drug Administration (FDA) for MDX-1401, a fully human antibody that targets CD30-positive lymphomas. MDX-1401 is enhanced for greater Fc receptor mediated antibody activity, one critical mechanism in tumor lysis by antibodies, using BioWa's Potelligent Technology.

The dose-escalation, multi-dose Phase I clinical trial is expected to enroll up to 36 patients with relapsed or refractory Hodgkin's disease. The trial is designed to establish and evaluate the safety profile and initial efficacy of MDX-1401. Preclinical *in vitro* studies showed that this second-generation nonfucosylated anti-CD30 antibody demonstrated enhanced antibody-dependent cellular cytotoxicity (ADCC), an important mechanism of action of therapeutic antibodies, and was active in inhibiting tumor growth in *in vivo* xenograft models.

"Today's announcement demonstrates our commitment to innovative approaches that have the potential to enhance our fully-human monoclonal antibody technology for developing important new therapies," said Irwin Lerner, Chairman of the Board of Directors and Interim President and CEO of Medarex. "We are pleased with our partnership with BioWa and with its technology as a method for increasing the potency of MDX-1401, a novel product that broadens our anti-CD30 clinical program for Hodgkin's disease."

"Medarex, one of our key strategic partners, continues to make exciting progress with Potelligent Technology," said Nobuo Hanai, President and CEO of BioWa. "We believe that this clinical development milestone is another demonstration of the significance of our antibody technology for generating and developing potentially important new therapeutics."

### **About Potelligent Technology**

Antibody-dependent cellular cytotoxicity (ADCC) activity is an important function of the human immune system, whereby immune cells can kill target cells, e.g. cancer cells. ADCC activity is one important mechanism underlying the efficacy of some currently approved anti-cancer antibodies. Enhancement of this activity is in the spotlight as one promising possibility for the next generation of antibody technology.

Potelligent™ Technology involves the reduction of the amount of fucose in the carbohydrate structure of an antibody. Research shows that Potelligent™ Technology significantly enhances binding affinity of antibodies for Fc receptors and increases ADCC activity *in vitro*. One potential benefit of Potelligent™ derived therapeutic antibodies is greater tumor cell killing activity than with conventional antibodies.

### **About BioWa**

BioWa is a wholly owned subsidiary of Kyowa Hakko Kogyo Co, Ltd, Japan's leading pharmaceutical and largest biotech company. BioWa is the exclusive worldwide licensor of Potelligent™ Technology. Potelligent™ Technology creates high antibody-dependent cellular cytotoxicity (ADCC) monoclonal antibodies. ADCC is a critical function of the immune system that enhances the ability of antibodies to kill tumor cells. The enhancement of ADCC is seen up to 100 fold *in vitro*. Both BioWa and Kyowa Hakko are currently developing ADCC enhanced monoclonal antibody-based therapeutics to fight cancer and other life threatening and debilitating diseases in various clinical stages. BioWa creates and develops enhanced ADCC antibodies for itself and others, offering a full range of antibody discovery and development capabilities. For more information about BioWa visit its web site at [www.biowa.com](http://www.biowa.com).

### **About Medarex**

Medarex is a biopharmaceutical company focused on the discovery, development and potential commercialization of fully human antibody-based therapeutics to treat life-threatening and debilitating diseases, including cancer, inflammation, autoimmune disorders and infectious diseases. Medarex applies its UltiMAb® technology and product development and clinical manufacturing experience to generate, support and potentially commercialize a broad range of fully human antibody product candidates for itself and its partners. With this announcement, thirty-six of these therapeutic product candidates derived from Medarex technology are in human clinical testing or have had INDs submitted for such trials, with six of the most advanced product candidates currently in Phase III clinical trials. Medarex is committed to building value by developing a diverse pipeline of antibody products to address the world's unmet healthcare needs. For more information about Medarex, visit its website at [www.medarex.com](http://www.medarex.com).

### **Cautionary Statement**

For Medarex: Except for the historical information presented herein, matters discussed herein may constitute forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to differ materially from any future results, performance or achievements expressed or implied by such statements. Statements that are not historical facts, including statements preceded by, followed by, or that include the words "potential"; "believe"; "anticipate"; "intend"; "plan"; "expect"; "estimate"; "could"; "may"; or similar statements are forward-looking statements. Medarex disclaims, however, any intent or

obligation to update these forward-looking statements. Risks and uncertainties include risks associated with product discovery and development, uncertainties related to the outcome of clinical trials, slower than expected rates of patient recruitment, unforeseen safety issues resulting from the administration of MDX-1401 in patients, uncertainties related to product manufacturing as well as risks detailed from time to time in Medarex's public disclosure filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the fiscal year ended December 31, 2005 and subsequent Quarterly Reports on Form 10-Q. There can be no assurance that such development efforts will succeed or that other developed products will receive required regulatory clearance or that, even if such regulatory clearance were received, such products would ultimately achieve commercial success. Copies of Medarex's public disclosure filings are available from its investor relations department.

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