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## **Novartis gains rights to promising hospital antibiotic in clinical development through full acquisition of Protez Pharmaceuticals**

- *Acquisition of Protez Pharmaceuticals provides rights to PZ-601 and further strengthens specialty medicines development portfolio in hospital infections*
- *PZ-601 a novel broad-spectrum antibiotic in Phase II development against potentially fatal drug-resistant infections – including MRSA and ESBL strains*
- *Antibiotic resistance an important public health problem, estimated to account for more than 100,000 deaths annually in the US and Europe together*
- *Novartis to fully acquire privately-held Protez for initial payment of USD 100 million, potential for up to USD 300 million of additional payments contingent upon success of PZ-601*

**Basel, June 4, 2008** — Novartis has signed a definitive agreement to acquire Protez Pharmaceuticals along with the rights in North America and Europe to PZ-601, a novel hospital antibiotic in clinical development. This transaction is subject to customary conditions for a transaction of this type.

The agreement with Protez, a privately-held US biotechnology company, based in Malvern, Pennsylvania, also provides Novartis with the company's research expertise.

PZ-601 is a new antibiotic in a class of agents known as carbapenems. Medicines in this class are useful in treating life-threatening infections caused by Gram-negative and Gram-positive bacteria. PZ-601, which is administered by injection, has been specifically shown to have a broad spectrum of activity that could offer better coverage over existing injectable antibiotics, especially against multidrug-resistant bacteria including MRSA (methicillin resistant *Staphylococcus aureus*) strains that are becoming an increasing public health challenge

“Novartis has a long-standing commitment of bringing innovative medicines to severely ill patients and fighting infections that represent significant public health threats,” said Joe Jimenez, CEO of Novartis Pharma AG. “The addition of Protez and its pipeline, including PZ-601, to our existing initiatives will further strengthen our position in the specialty field of hospital infections while helping to address the public health challenges of increasing bacterial resistance and high mortality rates.”

A 100-patient, Phase II study was started by Protez in May 2008 in the US to evaluate the safety and efficacy of PZ-601 in patients with complicated skin and skin structure infections including cellulites, abscesses, infected wounds and ulcers. Novartis plans to start additional clinical trials for PZ-601, with the aim of first regulatory submissions in 2012.

“This acquisition of Protez by Novartis underscores our company's infectious disease expertise and novel antimicrobial programs,” said Christopher Cashman, Protez President

and CEO. “We believe the growing presence of Novartis in the specialty field of hospital infections provides Protez the support required to fully execute its vision, advance its product pipeline and positively impact human health. We look forward to contributing to the strength of the global Novartis team.”

Antibiotic resistance is one of the world’s most pressing public health problems. According to the Centers for Disease Control and Prevention (CDC), two million people in the United States develop hospital-acquired infections each year, and approximately 90,000 die as a result. In Europe, an estimated three million hospital-acquired infections occur each year, resulting in some 50,000 deaths.

The number of bacteria resistant to antibiotics has increased significantly in the last decade, including the potentially fatal type known as methicillin-resistant *Staphylococcus aureus* (MRSA) – or “staph” – branded as a major public health threat in many countries.

Bacteria have also been observed with resistance to other antibiotics, including hospital antibiotics such as vancomycin (VRE). In addition, officials have documented multidrug-resistant bacteria known as extended-spectrum beta-lactamase enterobacteriaceae (ESBL) that are considered to be an increasing public health threat.

The addition of PZ-601 further expands the Novartis portfolio of specialty medicines for severe infectious diseases, which already includes approved medicines as well as development compounds for use in treating hospital-based infections and hepatitis.

Novartis markets Cubicin® (daptomycin) in Europe and various other markets for use in treating complicated skin and soft-tissue infections (cSSTI), right-sided infective endocarditis (RIE) due to *Staphylococcus aureus* (*S. aureus*) and *S. aureus* bacteremia (SAB) when associated with RIE or with cSSTI as well as other infections. Cubicin is the first of a new class of antibiotics called cyclic lipopeptides. Development projects involving hospital-based infections include Mycograb™ (antifungal), Aurograb™ (antibacterial) and Tifacogin (severe community-acquired pneumonia), three biotechnology compounds acquired in 2006 to treat life-threatening conditions.

### **Terms of the agreement**

Under terms of this innovative transaction, Novartis agrees to fully acquire Protez for USD 100 million. Protez’s owners are eligible for additional payments of up to USD 300 million, which are contingent upon clinical milestones, regulatory approval for PZ-601 and the achievement of commercialization targets. Dainippon Sumitomo Pharma Co., Ltd. is the IP holder of PZ-601 and retains the rights in other markets. This transaction with Protez is subject to customary conditions for a transaction of this type. Protez will operate as a stand-alone subsidiary of Novartis, continuing its operations in Malvern, Pennsylvania.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “potential,” “will,” “may,” “pipeline,” “could,” “would” or similar expressions, or by express or implied discussions regarding potential future earnings of Novartis or pending regulatory approvals, strategy, plans, expectations, intentions, potential synergies, strategic benefits or opportunities that may result from the proposed acquisition; or by express or implied discussions regarding potential approvals or labelling for, or future revenues from, PZ-601 or other products in Novartis’ or Protez’s portfolio. Such forward-looking statements reflect the current plans, expectations, objectives, intentions or views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, there can be no that the proposed transaction will be completed in the expected form or at all. Nor can there be any guarantee that PZ-601 will be

approved for any indications or labelling in any market or that PZ-601, or any other product in the Novartis or Protez portfolio, will achieve any particular levels of revenue in the future. Among other things, Novartis' expectations could be affected by unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

### **About Novartis**

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,200 full-time associates and operate in over 140 countries around the world. For more information, visit <http://www.novartis.com>.

### **About Protez Pharmaceuticals**

Headquartered in Malvern, Pennsylvania, Protez Pharmaceuticals is engaged in the discovery and development of new antibiotics for difficult-to-treat infections. Its focus is on highly differentiated intravenous and oral small molecule antibiotics to address increasing bacterial resistant and chronic or recurrent infections. For more information visit [www.protez.com](http://www.protez.com).

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