

## PRESS RELEASE

### **Bio-Gate offers effective infection prevention in human medicine with HyProtect™ technology**

- **Project partner launches study for CE approval of implants coated with HyProtect™**
- **Unique selling proposition due to extremely low infection rate**
- **Prevention of implant-associated infections**
- **HyProtect™ technology is able to solve prevalent and recurring problems in the field of infection prevention in human medicine**

**Nuremberg/Bremen, December 16, 2024 - Bio-Gate AG (ISIN DE000BGAG981), a leading provider of innovative healthcare technologies, is taking another important step towards the serial production of coated orthopaedic implants in human medicine with the imminent start of a study by a project partner.**

After receiving the approval from the first regulatory authorities and the leading ethics committees, a project partner of Bio-Gate AG will soon start a clinical study for the CE approval of revision implants coated with HyProtect™ in hip arthroplasty. The randomized, controlled trial (RCT) will be conducted with over 200 patients and is expected to be completed in 2027. The marketing of human implants coated with HyProtect™ is expected to start immediately after approval.

#### **Effectiveness of HyProtect™ already successfully tested in practice**

Bio-Gate's HyProtect™ coating has already been used in practice to help a large number of patients with prior (and repeated) implant-associated infections. More than 170 people worldwide have received implants coated with HyProtect™ as part of so-called individualized custom-made products / “compassionate care cases” in the USA

or treatment trials in Europe and Asia. These included patients who had undergone up to eight previous operations with repeated new re-infections. According to scientific studies, the infection rates for multiple revisions are over 50 percent. Contrary to this, patients who underwent surgery with HyProtect™ coated implants showed an extremely low re-infection rate.

### **High demand for infection prevention in human medicine**

Infection prevention is still a persistent problem in human medicine: According to the World Health Organization (WHO), more than 700,000 people currently die from infections with multi-resistant germs that cannot be successfully treated. The Norwegian Institute of Public Health (NIPH) estimates that the number of deaths will rise to 39 million by 2050.

The estimates are based on the fact that older people need operations more frequently, which leads to a higher incidence of infection without appropriate preventive measures. Between 2015 and 2050, the proportion of people over 60 in the global population will almost double from 12 percent to 22 percent. This means that by 2050, around two billion people will be aged 60 and over. In 2020, this figure was just one billion.

Another problem that will significantly increase the number of infections is the spread of germs that cannot be treated with antibiotics. While the number of these germs is constantly increasing, there is a large gap in the supply of new, effective antibiotics. Between 1985 and 2001, for example, no new antibiotic families were brought onto the market by the pharmaceutical industry. In the past 25 years, only six new classes of antibiotics have been introduced. Bio-Gate's HyProtect™ technology is also effective against multi-resistant germs - this has been confirmed in laboratory tests.

### **HyProtect™ coating reduces implant-associated infections**

Based on scientific findings, infections caused by foreign bodies, such as implants or catheters, are considered to be around 1000 times more severe than an infection without a foreign body. The HyProtect™ coating was developed precisely for this

purpose, to prevent so-called implant-associated infections. The HyProtect™ coating protects the surface of the implant with its antimicrobial effectiveness. Germs that come into contact with the surface are killed and thus prevented from multiplying. The surface of the implant can therefore not develop into a breeding ground for infections. The risk of reinfection is particularly high during revisions. The HyProtect™ coating can also contribute to significant cost savings in the healthcare sector. In Germany, an average of 16,000 euros is charged for conventional hip revision operations. If an infection with multi-resistant germs occurs, these costs rise to up to 120,000 euros.

In Bio-Gate's projects with global medical technology companies, the focus is on coating revision implants due to the urgent need. There are also plans to expand the HyProtect™ projects to include implants used in primary implant procedures. Bio-Gate AG is targeting the orthopaedic market with coatings for hips and knees, with a global volume of around 38 billion US-dollars by 2023. Market experts from Fortune Business Insights are forecasting an annual growth of almost eight percent until 2030. This development will be driven by rising numbers of orthopaedic joint replacements in the geriatric population.

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### **About Bio-Gate AG**

Bio-Gate AG is a medical technology company that develops and markets applications which use unique silver technologies to help prevent infections and thus to improve health. Bio-Gate AG's specialty is using pure silver to treat materials and surfaces that are used in all areas of daily life – thus providing long-term and medically effective protection against bacteria, microorganisms and other pathogens. Bio-Gate AG works in three fields to supply a variety of products that provide antimicrobial protection: material enhancement, surface coatings and the testing of antimicrobial or anti-adhesive properties of materials. The Nuremberg-based company offers systems that stretch across the entire value chain, from development to approval to production. For more information, please visit [www.bio-gate.de](http://www.bio-gate.de).

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