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聯康集團

Uni-Bio Science

UNI-BIO SCIENCE GROUP LIMITED

聯康生物科技集團有限公司*

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 0690)

VOLUNTARY ANNOUNCEMENT

MARKETING APPLICATION OF BOGUTAI® (TERIPARATIDE INJECTION) HAS BEEN OFFICIALLY APPROVED BY THE CHINA NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA) AS THE FIRST DOMESTIC DISPOSABLE PRE-FILLED PEN TERIPARATIDE INJECTION

On 22 January 2024, the board of directors (the “**Board**”) of Uni-Bio Science Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is delighted to announce that the China National Medical Products Administration (the “**NMPA**”) has approved the marketing application for the Group’s self-developed Bogutai® (teriparatide injection) on 16 January 2024. The application was accepted on 28 June 2022 with the approval number “Guoyaozhunzi (國藥准字) S20240004”. Bogutai®’s approval for marketing represents a significant milestone for the Company in the field of orthopedic diseases and expands the drug choices available to patients.

Bogutai® (teriparatide injection) is the Group’s fifth marketed product following GeneTime®, GeneSoft®, Pinup® and Boshutai®. It is also the first domestically produced disposable pre-filled pen teriparatide injection.

Both preclinical and non-clinical trials have demonstrated that Bogutai®’s biological activity is highly similar to that of the originator FORTEO, and the drug’s stability exceeds that of FORTEO. Clinical PK equivalence has also shown that Bogutai® is fully equivalent to FORTEO and offers a higher safety profile.

The ease of use, safety, and patient-friendly nature of Bogutai® are key differentiators of the product. The pre-filled injection pen design, developed in partnership with Swiss self-care giant Ypsomed, eliminates the need for reconstitution and additional purchases of injection pens. The extremely fine injection needles and high dose accuracy can significantly reduce patient discomfort during injection, thereby lowering operational barriers and improving patient compliance.

Teriparatide injection uses biological expression technology, and is a recombinant human parathyroid hormone analog (PTH1–34). It shares the same sequence as the 34-amino acid N-terminal of the 84 amino acid human parathyroid hormone, which is the biologically active region. This drug is used to treat postmenopausal women with osteoporosis who are at high risk of fractures.

Teriparatide has been available globally for over 20 years and has amassed extensive evidence-based medical data. It has demonstrated efficacy in new bone formation, bone density improvement, bone quality enhancement, and risk reduction of vertebral/non-vertebral and repeated fractures. It is the top choice for patients with extremely high fracture risks.

In 2020, the FDA removed the black-box warning from the originator teriparatide FORTEO, which previously indicated a potential risk of osteosarcoma. The FDA also lifted the restriction limiting patient’s treatment duration to beyond 24 months. These changes further highlights the effectiveness and safety of the product, as well as significantly expands the access to many more patients.

According to a national osteoporosis epidemiological survey, the prevalence of osteoporosis in individuals over 50 years old is 19.2%, with 32.1% in women. For people over 65, the prevalence rises to 32.0%, with 51.6% in women. As per the “**Primary Osteoporosis Diagnose and Treatment Guideline (2022)**”, the current prevalence of osteoporosis in China is approximately 90 million, about 70 million of whom are women. Fractures related to osteoporosis are highly damaging and are a leading cause of disability and death in older patients. It is projected that China’s medical cost for major osteoporosis fractures (wrist, vertebral and hip) will reach RMB132 billion by 2035, and further rise to RMB163 billion by 2050.

Looking ahead, the Group is confident in leveraging its cost advantages and superior market operation capabilities to develop Bogutai® into a blockbuster product that significantly contributes to revenue growth.

On behalf of the Board
Uni-Bio Science Group Limited
Kingsley Leung
Chairman

Hong Kong, 22 January 2024

As at the date of this announcement, the Board comprises four executive Directors, namely, Mr. Kingsley Leung (Chairman), Mr. Chen Dawei (Vice-Chairman), Mr. Zhao Zhi Gang; one non-executive Director, Mr. Yau Kwok Wing Tony; and three independent non-executive Directors, namely, Mr. Chow Kai Ming, Mr. Ren Qimin and Mr. Ma Qingshan.

* *For identification purpose only*