

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**Uni-Bio Science Group Ltd.**

**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**

### **rhPTH 1-34 PHASE III**

### **CLINICAL TRIAL RESULTS**

#### **I. IMPORTANT NOTICE**

1. Reference is made to the announcement (“**Announcement**”) of Uni-Bio Science Group Limited (the “**Company**”), together with its subsidiaries, (the “**Group**”) dated 21 March 2014. Unless otherwise specified, terms used herein shall have the same meaning as those defined in the Announcement.
2. Information disclosed in this announcement is the results of the efficacy analysis from the clinical trial entitled rhPTH 1-34 Phase III Clinical Trial (“**Uni-PTH Clinical Trial**”). The Group’s rhPTH 1-34 (“**Uni-PTH**”) is a prescription new drug and is an effective anabolic (bone growing) agent to treat osteoporosis. The statistical results disclosed of this announcement were provided to the Group by an independent statistical group as of the date of this announcement.
3. This announcement is prepared in both English and Chinese. In the event of discrepancy, the Chinese version shall prevail.

\* For identification purposes only

## **II. EXECUTIVE SUMMARY OF UNI-PTH CLINICAL TRIAL**

### **1 Background**

In the Uni-PTH Clinical Trial, Calcichew D (contains calcium carbonate 1250 mg (equivalent calcium 500mg) per tablet + 200 IU of Vitamin D3, one tablet per day) was used as basic treatment and positive control group was treated with Calcitonin (20IU, subcutaneous, once weekly injection). Randomized, open-label, multi-center trial design was implemented to evaluate the efficacy and safety of the Uni-PTH (20 µg, subcutaneous, once daily injection) in post-menopausal women with osteoporosis. Primary endpoint is the change of bone mass density in lumbar spine after 12 months of treatment, secondary endpoints include changes in serum bone-specific alkaline phosphatase (BSAP), urinary N-telopeptide of type 1 collagen (uNTX)/urine creatinine (uCr), and number of fractures. Safety was also evaluated. A total of 502 patients were enrolled with written informed consent and randomized in a 3:1 ratio to receive Uni-PTH (treatment group, n=375) or calcitonin (positive control group, n=127). The Uni-PTH Clinical Trial was led by Shanghai ChangZheng Hospital (上海長征醫院) with the participation of 10 other hospitals. Statistical analysis was performed by the Department of Health Statistics, Second Military Medical University (第二軍醫大學衛生統計學教研室). Biochemical markers of bone turnover (i.e. BSAP, uNTX/uCr) were measured by the central laboratory at the Shanghai First People's Hospital (上海市第一人民醫院).

### **2 Clinical Trial Objectives**

In a phase II trial sponsored by the Group, Uni-PTH has successfully shown to increase lumbar spine bone mass density after 6 months of treatment. The objective of the phase III is to further validate the efficacy and safety results of the drug from the phase II clinical trial. Mode of administration and dosage is consistent to that of the phase II clinical trial.

### **3 Clinical Study Results**

#### *3.1 Patient comparability*

Patients in the treatment and control group have similar bone density, demographic characteristics, vital signs, blood biochemical test and other laboratory test parameters at baseline. There were no statistically significant differences ( $P>0.05$ ).

### 3.2 Clinical results

| <b>Endpoint</b>                | <b>Type</b> | <b>Comparison</b>                                           | <b>Positive control*<br/>(n=127)</b>          | <b>Treatment group*<br/>(n=375)</b>           | <b>Statistical significance difference between groups</b> |
|--------------------------------|-------------|-------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------------------|
| Lumbar spine bone mass density | Primary     | Difference between both groups after 12 months treatment    | 2.78%                                         | 6.92%                                         | Met – significant increase (P<0.01)                       |
| BSAP                           | Secondary   | Difference between BSAP at baseline (T=0) and 12 months     | Decrease (18.02 µg/L to 15.60 µg/L)           | Increase (18.19 µg/L to 19.96 µg/L)           | Not applicable                                            |
| uNTX/uCr                       | Secondary   | Difference between uNTX/uCr at baseline (T=0) and 12 months | Decrease (15.46 nmol/mmol to 14.24 nmol/mmol) | Increase (13.08 nmol/mmol to 19.24 nmol/mmol) | Not applicable                                            |
| Fracture rate                  | Secondary   | Difference between both groups after 12 months treatment    | 3.97%                                         | 3.78%                                         | Not met – no significant difference (P=1.0)               |
| Safety**                       | Secondary   | Difference between both groups after 12 months treatment    | 16.54%                                        | 20.86%                                        | No significant difference (P=0.37)                        |

\* FAS data

\*\* Rate of adverse events

### 3.3 *Safety*

Incidence of adverse events (AEs) is consistent with the safety data from the prior phase II study of Uni-PTH, as well as data reported in literature. Most common AEs include headache, dizziness and rash.

## 4 **Conclusion**

The phase III clinical trial results confirm that the Uni-PTH is safe and efficacious in post-menopausal women with osteoporosis. Uni-PTH met primary endpoint of increasing bone mass density of lumbar spine after 12 months of treatment. In addition, Uni-PTH continues to exhibit a safe AE profile, consistent with past trials and that of similar drugs.

The biochemical biomarker results clearly indicate calcitonin has a different mechanism of action from parathyroid hormone. Being anti-resorptive, calcitonin decrease uNTx/uCr and a reduction in urinary NTx secretion provides evidence of compliance and drug efficacy. On the other hand, biomarkers of BSAP and resorption (uNTx/UCr) were increased by Uni-PTH, supporting its role as an anabolic agent to promote bone growth.

Currently, all available treatments used for osteoporosis patients are anti-resorptives – they slow down bone turnover, which in turn results in a slowing down of bone loss. However, Uni-PTH is in the only class of available treatment that stimulates new bone formation and actively rebuild weakened bones. The introduction of Uni-PTH into the market may change the treatment paradigm of osteoporosis in China, providing an alternative and more effective treatment that helps reverse or slow the progression of osteoporosis. The new treatment is especially important for patients with severe osteoporosis, where other treatments already have no effect on disease progression and no alternatives are available.

## III. **THE GROUP'S NEXT ARRANGEMENTS**

We plan to finalize the clinical trial summary report of the Uni-PTH Clinical Trial and submit the NDA to the Chinese Food and Drug Administration (CFDA) before end of year 2014.

#### **IV. RISK WARNINGS**

The Group plans to submit the NDA to the CFDA before 2014 year end. In the case that the CFDA requires the Group to provide supplemental research data, this may lead to extension of the time required for approval.

The results of the Uni-PTH Clinical Trial do not automatically mean an approval from the CFDA will be obtained. The approval of Uni-PTH is subject to the final decision of the CFDA.

The Company will continue to pay close attention to the relevant progress of NDA submission of Uni-PTH and will make announcement as and when appropriate.

By Order of the Board  
**Uni-Bio Science Group Limited**  
**Tong Kit Shing**  
*Chairman*

Hong Kong, 30 June 2014

*As at the date of this announcement, the Board comprises two executive Directors, namely, Mr. Tong Kit Shing (Chairman) and Mr. Kingsley Leung; one non-executive Director, namely, Mr. Fung Kwok Leung; and three independent non-executive Directors, namely, Mr. Tsao Hoi Ho, Terry, Dr. Carl Aslan Jason Morton Firth and Mr. Zhao Zhi Gang.*