Oneness Biotech Co Ltd

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James Chen: Ladies and gentlemen, thanks for your time joining Oneness Biotech's presentation today. The main speaker for this session will be Dr. Nien Yi Chen, Head of Antibody Development. Dr. Chen, I'll hand it over to you if you are ready.

Dr. **Nien Yi Chen:** Thank you, James. Good morning everyone. I'm glad to be here to share the progress and the outlook of Oneness Bio. On the slide number two, it's described for your references. Slide number three, the core values of Oneness Bio.

Oneness Bio is a limited biotech company in Taiwan. Standing on solid scientific basis, Oneness is committed to developing new drugs to fulfill our medical needs, oncological, dermatological, immunological and the infectious diseases. Science, integrity and the transparency are the core values that we present our attitude to the drug development, shareholders and the partners.

Slide number four. Oneness Bio was established in 2008. IPO issued in 2011. In 2016, PIC/S GMP manufacturing plant was built. They can supply ON101 drug product for global market. In 2020, the first global licensing deal of FB825 were made, while the promising phase III study results of ON101were announced in the same year.

During the last 10 years, the market cap growth is going from eight million to three billion US dollars. Oneness Bio is now in fast-growing stage.

Slide number five. 2020 is the year of transformation of Oneness Bio. We stepped into global market with three achievements. First, FB825, anti-CemX antibodies were all licensed to LEO pharma for 530 million USD, upfront and the milestones.

Secondly, ON101a diabetic foot ulcer new drug achieved a positive phase III study result. NDA is about to be received from Taiwan FDA. Finally, Oneness launched the GDS in 177 million USD. Today, Oneness is one listing in Taipei Exchange and the Luxembourg Stock Exchange.

The following slides are the financial report from slide 6 to slide 13. Slide seven shows the financial report for your reference. The market cap for Oneness now is approximately 2.9 million USD. Slide number eight is the consolidated statement of comprehensive income.

The majority expense came from R&D and tech piece. Most are from a cultural study, multiple international clinical studies and the production of study drugs. The R&D expenditure contributed to 78 percent of total operation expenses in 2019. Accumulated R&D expenditure in 2020 Q1 to Q3 accounted for 82 percent of total operation expenses.

Slide number nine shows the consolidated balance sheet. Oneness Bio has a healthy balance sheet with sufficient cash flow and low liabilities. Oneness Bio launched GDS offering for 177 million USD in October next year, which will speed up drug development for investment.

Slides 10 to 12 are the summary of consolidated financial statements for your reference. The slide number 13, here we proceed to R&D highlights. The slide number 14 shows the new drug pipeline of Oneness Bio.

Oneness Bio's new drug pipeline is covering from NDA and the discovery stage for medical needs. The first pipeline, ON101, is a topical cream for diabetic foot ulcers. It will be the most effective treatment for DFU.

NDA has been submitted to Taiwan FDA, pre-NDA working with an NPA, China FDA was completed. We are planning to submit the NPA package. Also we are planning to launch ON101 in APAC area and initiate a US trial in 2020, '21.

FB825 is a novel antibody treatment, tapping into CemX segment of IgE cell. With the outstanding efficacy and unique mechanism of action, LEO Pharma entered a global licensing deal with Oneness for FB825. We aim to complete US phase 2A study in atopic dermatitis in 2021 and the Taiwan phase 2A study in allergic asthma in 2022.

FB704A is an anti-IL-6 fully human antibody. It is the first biologics exploring in severe neutrophilic asthma, which so far there is no specific treatment available on the market. OB318 is a highly purified compound derived from fermentation of a special fungus in Taiwan. Currently, phase I study is ongoing in Taiwan for HPTC patients. It aims to be completed in 2021.

FB918 is an anti-interlukin-33 fully human antibody with a different mechanical action from any

other clinical candidates. Other funding is expected in 2022.

The last part of our pipeline in the discovery stage is SNSA1-2. It is an auto-nucleotide base antivirus new drug co-developed with Oneness Bio and Microbio Shanghai. With these pipelines, Oneness maintains continuous profitability and long-term development.

In the following slides key pathways are introduced. On slide 15, ON101 is a new drug ready to market for the diabetic foot ulcer. It will be the first new drug to be approved for diabetic foot ulcer since 1997. There are more than 30 million DFU patients worldwide with medical expenditure that's greater than 100 billion USD, so DFU is a main medical need globally.

Slide 16 shows the primary endpoints of the phase III MRCD study of ON101. The instance of wound closure in week 16. Active treatment is the ON101 and the comparative is the typically and commonly used for therapy Aquacel Hydrofiber Dressing, AHD.

In FAS group, 60.7 percent of subjects reached complete healing in week 16 compared with 35.1 in AHD with p-value at .001.

In MITD group, 61.9 percent of subjects completed healing compared to 33.9 percent in AHD group with the P-value of less than .001. The complete healing rate of ON101 is significantly superior to Aquacel. The slide number 17 illustrates the secondary endpoint, time to wound closure.

The difference of time to wound closure become obvious between the two groups starting from week eight. 30 percent of patients in ON101 group achieved complete healing in 10 weeks, which is four weeks ahead compared to the AHD group that achieved in 14 weeks. The p-value in the two groups in time to the wound closure is .002.

Slide 18 shows the robust and the consistent efficacy of ON101 across hard-to-heal ulcers. Among the subgroup of regular patients were difficult-to-treat wounds. Patient was pooled by control HbA1c more than seven percent, BMI greater or equal to 35.

Larger wounds more than 5 cm2. Also, longer than six months duration. Current smokers, and the patient with neuropathy. All of them showed superior effects over AHD group across all subgroups.

On the slide 19, DFU become chronic, because hyperglycemia cause the immuno-neuropathy in

diabetic patients. This triggers imbalance in the M1, M2 macrophage in diabetic skin. When the tissue is damaged, M1 macrophage becomes excessive and the prolonged inflammation stage. Correlated information delays M1, M2 macrophage transition and that delays the wound healing process.

On the slide 20, we reveal the modal action of ON101. M1, M2 macrophage, the transition is inhibited by interlukin-1 beta, TNF-alpha, IL-6 in chronic wounds. ON101 can reduce IL-6 and IL-1-beta levels.

ON101 treatment suppressed M1 macrophage related to gene expression and deactivated the M2 macrophage related to genes. Those data demonstrated that ON101 can restore the balance of M1, M2 macrophage and bring the chronic wound balance impaired back to the normal wound healing.

On the slide 21, ON101 is revolutionary DFU treatment. Current standard of care of treatment consists of endless cycle of debridement and dressing that only gives remission. With the application of ON101, if you can be treated to completely heal instead of remission only, all around it will be the most effective treatment for DFU that is going to the change DFU treatment dialogue.

On slide 22, ON101 provide a remedy here in a cost-effective way. Based on the values of the wound size, two to seven tubes of ON101 are required for the patient to acquire complete healing within two to three months.

Slide 23 is the comparison of ON101 to other pharmaceutical and the devices on the market. Two to five tubes of ON101 can provide DFU patient with complete healing. It's convenient to use at home and the storage is at room temperature. With Oneness there's a DFU trial in the United States but not available in most countries and so there's a limited healing effect in DFU.

Of these advantages there is storage completion at 2.8 degrees Celsius. Other medical devices such as massive debridement therapy, hyperbaric oxygen therapy, skin graft are expensive and time-consuming and they need to be practiced in hospitals with multiple sessions. ON101 will be the solution to provide an effective, convenient and affordable treatment for a medical need in DFU.

Slide 24, DFU is a complex chronic wound that makes its leading cost to the severity and the risks of diabetic patients. DFU is the most expensive amount of diabetics' complications. That is

compared to the cancers. A low-limb amputation on diabetic patients occurs every 20 seconds globally. The survival rate of DFU amputee is listed at 60 percent.

In summary, on slide 25, ON101 is the best DFU new drug with robust efficacy. NDA approval is expected in Taiwan with global market extension anticipation. NDA submission is planned for China and Asia. PIC/S GMP facility is ready for global supply with capacity of 25 million tubes per year.

Second, phase III trial in United States, as suggested, will be initiated in Q1 2021. Slide 26, we are talking about FB825. FB825 is the first-in-class monoclonal antibody for atopic dermatitis and may apply to other allergic diseases. It has entered a global licensing deal with LEO Pharma.

Slide 27 shows the unique mode of action of FB825. IgE comes from IgE B cells. With the stimulus of allergens B cells will be activated and become IgE cells. FB825 is a humanized monoclonal antibody that body that binds to the CemX domain of membrane-bound IgE. Clinging to the paths of IgE B cells by inducing apoptosis and ADCC.

FB825 is a first-in-class new drug with a unique mechanism by targeting CemX on IgE cell to effectively control the IgE mediation it induces including atopic dermatitis and asthma.

Slide 28. Sanofi 's Dupixent is the fastest-selling biologics drug for moderate to severe atopic dermatitis. In our first inpatient study, FB825 demonstrated its cost-effective dose advantages through the comparison with different trials of Dupixent.

We have seen that with only two doses, FB825 can help 67 percent of patients with AD symptoms in 16 weeks. While nine injections of Dupixent are needed to reach 62 to 69 percent AD symptoms.

Slide 29. In the end of 2020, FDA announced a positive result of Rinvoq in patients with AD. Based on the results of a head-up study, Rinvoq dose daily has 71 percent reach EASI-75 at week 16 comparing to Dupixent dose every two weeks with 61 percent. FB825 dose every 12 weeks achieved a similar effect in 67 percent in EASI-75.

FB825 is not only competitive in efficacy and the more convenient for use than the Dupixent and Rinvoq, but also superior in safety profile.

Slide number 30. There is a huge demand in AD treatment. Biologics continue to dominate the

AD treatment market. The cumulative sales of Dupixent in three quarters of 2020 is in excess of â,¬2.5 billion. The sales of this year is projected to excess â,¬3.5 billion. Sanofi's peak sales in 2028 will reach over â,¬10 billion, of which AD accounts for â,¬6 billion.

Slide 31, FB825 provides a cost-effective treatment in AD with safety profile. FB825 have a potential to be given every month or every three months a dose. Side effects were minor in available clinical studies.

Dupixent is dosed every two weeks with the potential of increased side effects. Rinvoq has a black-box warning in the drug label for rheumatoid arthritis stating it "may increase the risk of serious infection, malignancy and also thrombosis." We are confident that FB825 has good efficacy and a safety profile which will be a better option for the AD as AD is a chronic disease that needs life-long treatment.

Slide 32 shows the clinical timeline for a large allergic asthma phase 2A study. Only one biologic, Xolair, approved since 2003. FB825 is happy to compete by addressing IgE-related diseases. Asthma study aims to initiate in early this year recruiting 100 subjects and to follow it until 2022.

Slide 33, in the early 2020, LEO, Oneness Bio and Microbio Shanghai entered a worldwide exclusive agreement covering the development and the commercialization of novel atopic dermatitis and asthma drug candidate FB825.

This aligns FB825 will be expedited to commercialization with the fuel of the global team of professional expertise. Under the terms of the agreement, LEO Pharma will make upfront of 40 million USD and the milestone payment up to 419 million USD, followed by here in rows.

Together, LEO, Oneness and the Microbio Shanghai will explore the treatment of IgE and related diseases in proving AD, allergic asthma and FB825 can best address and deliver the solution to the patients.

Slide 34, the following slide will outline for the early-stage pipeline for FB704A, OB318, FB918, and SNSA1, A1-2.

Slide 35. There are many biologics approved for eosinophilic asthma. While there are no biologics available for neutrophilic asthma. IL-6 is the key cytokine for neutrophilic asthma. FB704A neutralized IL-6 and it can potentially block the parthenogenesis of neutrophilic asthma. Phase 2A study is planned to be initiated in early 2021. We aim to complete the study by the end

of this year.

Slide 36. The neutrophilic asthma is a new category of asthma in this area. Approximately 110 million patients in the world. Severe neutrophilic asthma affects 5.5 million patients worldwide. To achieve control of severe neutrophilic asthma remains a medical dream. Effective biologic treatment will be an 18 billion market potential.

Slide 37 compares it with early pipelines. Obviously 1A, the Americans start a phase I study in row seven, with late-stage existing patients, study to be completed in 2022. FB918, a fully human monoclonal antibody is to be available for our FB918 analysis and FDA filing expected in 2022.

To enrich the pipeline with our drug development platform, we are developing specific antibodies for biologically based and autoimmune type drugs for infectious disease. On the slide 38, in 2021, we are expecting ON101 to enter China and APAC market as well as it rises into the international company for its development and commercialization globally.

The development of FB825 is ongoing and in the next month we will have achieved on the completion of A2A study in AD.

Slide 39. Oneness Bio is utilizing its own technology platform to develop robust drug pipelines. Solid financial standing fully supports the experienced R&D team to deliver new solutions for our medical needs. Finally, I wish you all a safe and healthy for all of you in 2021. Thank you.

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