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China's Connect Eyes Partnerships To Globalize Dermatitis Biologic

CEO Wants To Unlock Main Value Outside Home Market

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- **INTERVIEWS**

Executive Summary

By Brian Yang

Watch out Sanofi. US- and China-based Connect BioPharma is looking to position its novel biologic for atopic dermatitis to compete head-on with best-selling Dupixent both inside and outside China in an increasingly crowded space, says co-founder and CEO Wei Zheng in an exclusive interview with *Scrip*.

*Source: Shutterstock*CONNECT BIOPHARMA EYES PARTNERSHIPS TO BRING NOVEL BIOLOGICS FROM CHINA TO GLOBAL MARKET

Some 10 years after its founding, China- and US-based Connect Biopharma Holdings Ltd. is readying a major regulatory filing for its lead candidate, a novel anti-interleukin 4 receptor alpha

antibody for moderate to severe atopic dermatitis it hopes will be able to take on Sanofi's blockbuster biologics in the space.

The atopic dermatitis area is seeing increasing activity from conventional topical treatments to biologics, from local to systemic therapies, and is a segment that has attracted a flurry of new drug approvals both inside China and globally.

The reasons are multiple. The autoimmune condition has a high occurrence but also recurrence, while treatment options before the launch of effective systemic biologics were mostly topically and locally applied ointments.

Connect's own novel biologic for atopic dermatitis, CBP-201, is moving ahead as one promising candidate and company co-founder and CEO Zheng Wei disclosed in an exclusive interview that work on a new drug application filing with China's Center for Drug Evaluation is now underway.

Zheng said Connect is working on pre-NDA meetings with the new drug review wing of the country's National Medical Product Administration and had submitted interim results from a 16-week pivotal Chinese clinical study, which showed the drug met all endpoints.

The executive believes the novel biologic could differentiate itself from Sanofi's IL-4 receptor alpha and -13-targeting antibody Dupixent (dupilumab) as it binds to a different region of the site.

'Higher Potency'

Connect has sites in Taicang, Jiangsu, China and San Diego and US-based Zheng told *Scrip* that CBP-201 also differs from dupilumab by offering "higher potency."

A global Phase IIb trial showed that all three CBP-201 arms, with a total of 216 enrolled patients receiving 300mg once every two weeks, 150mg once every two weeks or 300mg once every four weeks, met it primary endpoint of eczema area and severity index (EASI) percent reduction from baseline at week 16, showing statistical superiority to placebo. The company plans to start a global Phase III study in the second half of 2022.

Meanwhile in China, the Center for Drug Evaluation has indicated that data from the China trial — the largest to date in the country in the drug class — could be sufficient for a new drug application submission. Zheng noted. The 16-week results reported in October showed that the at least two grades of reduction at week 16 from baseline was significantly greater for CBP-201 in the 300mg every two week dose group, with 30.3% of patients showing improvement, compared to 7.5% for placebo ($p<0.001$).

However, some dermatology experts noted that although efficacy was demonstrated, comparison with placebo rather than a head-to-head trial with dupilumab left room for improvement.

ISO Partnerships, Funding

Zheng said the company's goal is to go global through worldwide or regional partnerships and to secure new funding. "The majority of our value will be realized outside China, in the global market," he predicted.

That's because people affected by the recurring skin condition range from infants to children to adults. Compared to topical treatments, systematic drugs such as biologics can be more effective in patients with a large affected body surface, which can be up to 50% for some patients.

As for fundraising, Zheng said the company aims to remain "within its vision and capability" and is looking for intellectual property rights partnerships with both regional and global companies, as well as commercialization partners.

"An ideal commercial partner would be both in China and global, with experience in biologics and auto-immune conditions," he observed.

New Competitors

Annual global sales of biologics for atopic dermatitis are already worth more than $6bn and the market is growing, driven by recent approvals and launches.

Globally, Dermavant Sciences Inc. is developing its aryl hydrocarbon receptor agonist Vtama (tapinarof) in a Phase III study, after securing a previous US approval for plaque psoriasis.

Arcutis Biotherapeutics, Inc. is developing Zoryve (roflumilast), a small molecule topical PDE4 inhibitor, after a US launch earlier this year for plaque psoriasis. (Also see "Arcutis's Zoryve Succeeds In Second Phase III In Atopic Dermatitis" - Scrip, 12 Dec, 2022.)

Inside China, Shenzhen Celestial Pharmaceuticals Ltd., a subsidiary of Guangzhou-based Zhonghao Bio, gained a global first approval for benvitimod, a novel aryl hydrocarbon receptor immunomodulator, as a twice-daily 1% ointment. Since then, the drug has been included in the National Reimbursement Drug List following price negations with the National Health Security Administration.

Similarity, Sanofi has also secured national insurance coverage for Dupixent in China.

Although it's hard to predict precisely, Connect's Zheng said the discussion of the NDA filing for CBP-201 with China's National Medical Products Administration should be within the next two to three months.

Meanwhile, the firm is planning a global Phase II study with the drug in asthma, which aims to enroll 300 patients.