



Zenas BioPharma Announces Strategic License and Collaboration Agreement with Bristol Myers Squibb

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Zenas BioPharma Announces Strategic License and Collaboration Agreement with Bristol Myers Squibb to Develop and Commercialize Novel Bi-Functional Antibody Obixelimab in Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia

Collaboration furthers Zenas' vision to bring innovative immunology-based medicines to patients around the world by leveraging Bristol Myers Squibb's long-standing expertise in immune-mediated diseases

Zenas will receive a \$50 million up-front cash payment and an equity investment from Bristol Myers Squibb, along with additional potential milestone-based payments and royalties in the licensed territory

WALTHAM, Mass, September 5, 2023 (GLOBE NEWSWIRE) – Zenas BioPharma, a global biopharmaceutical company committed to becoming a leader in the development and commercialization of immunology-based therapies, today announced that it has entered into a license and collaboration agreement with Bristol Myers Squibb Company to develop and commercialize obixelimab for autoimmune diseases in Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia.

Obixelimab is an investigational bifunctional, non-cytolytic, humanized monoclonal antibody that binds CD19 and FcγRIIb to inhibit B cells, plasmablasts, and CD19-expressing plasma cells. Obixelimab is currently being studied as a subcutaneous injection in a global Phase III trial in patients with IgG4-Related Disease (IgG4-RD), a disease for which there are currently no approved treatments. The compound is also being studied in a global Phase II/III trial in patients with warm antibody Auto-Immune Hemolytic Anemia (wAIHA).

"This collaboration marks an important step forward in realizing our vision for obixelimab to benefit patients living with auto immune diseases globally," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas BioPharma. "The deeply experienced and passionate team at Bristol Myers Squibb is an ideal partner based on their proven development, regulatory and commercial capabilities in Japan and throughout the licensed territory.

"This collaboration represents an important opportunity to address unmet needs for people living with IgG4-RD, for which there are no approved treatment options," said Steve Sugino, Senior Vice President & General Manager, Japan, Bristol Myers Squibb. "We are excited to work with Zenas BioPharma to expand the reach of obixelimab in the licensed territory and to make an impact on the lives of patients that are waiting."

Under the terms of the license agreement, Zenas will receive a \$50 million up-front cash payment and is eligible to receive additional payments in connection with the achievement of certain development, regulatory and commercial milestones, as well as royalties on net sales of obixelimab in the licensed territory. In exchange, Bristol Myers Squibb will receive exclusive rights to develop and commercialize obixelimab in the licensed territory. In addition, Bristol Myers Squibb is making an equity investment in Zenas.

About Obixelimab

Obixelimab is an investigational Phase 3-stage, bifunctional, non-cytolytic, humanized monoclonal antibody that mimics the action of antigen-antibody complexes by binding CD19 and FcγRIIb to inhibit B-lineage cell activity. In several early-stage clinical studies, including in various autoimmune diseases, 198 subjects were treated with obixelimab. In these clinical studies, obixelimab demonstrated inhibition of B cell function without depleting the cells, resulting in encouraging treatment effect in patients with various autoimmune diseases. Zenas acquired exclusive worldwide rights to obixelimab from Xencor, Inc.

More information on the Phase 3 (INDIGO) study for the treatment of IgG4 Related Disease is available at [clinicaltrials.gov: NCT05662241](https://clinicaltrials.gov/ct2/show/study/NCT05662241). More information on the Phase 3 (SAPHiAre) study is available at [clinicaltrials.gov: NCT05786573](https://clinicaltrials.gov/ct2/show/study/NCT05786573).

About IgG4-related disease

IgG4-RD is a chronic, immune-mediated fibro-inflammatory disease that can affect multiple organs including the major salivary glands, orbits, lacrimal glands, pancreas, biliary tree, lungs, kidneys, and retroperitoneum. Approximately 20,000 patients are diagnosed with IgG4-RD in the United States alone. Despite its increasing recognition, there remains a need for further research and effective therapeutic options for individuals living with this debilitating disease.

Across the world, the use of glucocorticoids is widely considered to be the standard of care for treating IgG4-RD. There are no approved treatment options for this condition. While commonly used, glucocorticoids and available B cell depleting therapies rarely lead to long-term, treatment-free remissions, and are associated with a high risk of toxicity in these patients. Such therapies may also impair vaccine responses, including those for SARS-CoV-2 and influenza.

About Zenas BioPharma

Zenas BioPharma is a global biopharmaceutical company committed to becoming a leader in the development and commercialization of immunology-based therapies for patients around the world. With clinical development and operations globally, Zenas is advancing a deep and balanced global portfolio of potential first- and best-in-class autoimmune therapeutics in areas of high unmet medical need while meeting the value requirements of the dynamic global healthcare environment. The company's pipeline continues to grow through our successful business development strategy. Our experienced leadership team and network of business partners drive operational excellence to deliver potentially transformative therapies to improve the lives of those facing autoimmune and rare diseases. For more information about Zenas BioPharma, please visit www.zenasbio.com and follow us on Twitter at [@ZenasBioPharma](https://twitter.com/ZenasBioPharma) and [LinkedIn](https://www.linkedin.com/company/zenasbiopharma).

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