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# Bio-Thera And Intract Partner For Oral mAb Project

*Chinese Biosimilars Specialist Licenses Soteria And Phloral Drug Delivery Technologies*

by **David Wallace**

Chinese biosimilars specialist Bio-Thera Solutions has struck a licensing deal with Intract Pharma that will give it access to drug delivery technologies that will be used to develop novel oral monoclonal antibody treatments for gastrointestinal inflammatory indications.

Chinese biosimilars developer [Bio-Thera Solutions](#) has announced plans to develop “novel oral monoclonal antibody treatments for chronic gastrointestinal inflammatory diseases,” after striking a deal with [Intract Pharma](#) that will give it access to its Soteria and Phloral drug-delivery technologies.

According to Bio-Thera, the “global collaboration and license agreement” with Intract will see Bio-Thera granted a “worldwide license to Intract’s oral biologics drug delivery platform for a single undisclosed mAb product.”

Under the terms of the deal, Intract will receive an undisclosed upfront payment, with potential development and commercial milestone payments along with royalties on product sales.

Intract will lead the pre-clinical research for the product, with Bio-Thera then having an option to expand development of the product for multiple GI indications. Bio-Thera will be responsible for manufacturing and commercialization of any approved products.

Noting that Intract’s oral biologics delivery platform “includes Soteria, a technology which protects proteins such as mAbs from degradation in the intestinal lumen,” Bio-Thera said the

platform “also includes Phloral, a clinically-validated technology that utilizes both pH and the enzymes produced by colonic bacteria as a trigger mechanism to allow accurate release of payloads in the colon, a suitable site in the GI tract for targeting of biologics for local and systemic delivery.”

Bio-Thera CEO Shengfeng Li said that developing oral biologics represented “the next step in advancing compliance and access to innovative mAbs for chronic diseases,” adding that “we believe that combining Bio-Thera’s antibody expertise with Intract’s oral delivery platform will lead to a great advance in the treatment of gastrointestinal disease.”

Meanwhile, Intract CEO Bill Lindsay said the firm was “delighted to be partnering with Bio-Thera to address the significant challenge of delivering powerful biologics orally.”

“We believe that our technologies will allow development of a more effective therapeutic for the treatment of IBD,” Lindsay suggested, “while also increasing drug safety and reducing cost.”

### **Follows Celltrion Deal For Oral Infliximab**

The deal is not the first time a major biosimilars producer has allied with Intract to develop an oral product. A year ago, Celltrion struck a deal with the company to develop an oral formulation of infliximab for the treatment of inflammatory bowel disease. (Also see "[Celltrion Partners With Intract Pharma For Oral Infliximab](#)" - Generics Bulletin, 25 Aug, 2020.)

Providing a recent update on the project, HoUng Kim, head of Celltrion Healthcare’s medical and marketing division, told *Generics Bulletin* that the product was “currently undergoing pre-clinical trials,” with the project aligning with Celltrion’s goal to “pioneer uncharted areas of innovative therapies, incorporating unique and successful next-generational approaches.” (Also see "[Celltrion’s Kim Emphasizes Innovation As Pipeline Grows](#)" - Generics Bulletin, 29 Jun, 2021.)

Separately, BioFactura recently reached an agreement with fellow US-based biotech Rani Therapeutics to explore formulating its BFI-751 proposed biosimilar to Stelara (ustekinumab) using Rani’s proprietary RaniPill ‘robotic’ pill technology, which intends to replace subcutaneous or intravenous injection of biologics with pain-free oral dosing. (Also see "[BioFactura’s Ustekinumab Biosimilar To Be Tried As ‘Robotic’ Pill](#)" - Generics Bulletin, 14 Sep, 2021.)

Bio-Thera has been active on the deals front in recent weeks. A licensing agreement with Hikma for its BAT2206 biosimilar ustekinumab candidate – announced in late August (Also see "[Hikma’s US Biosimilars Ambitions Begin With \\$150m Ustekinumab Deal](#)" - Generics Bulletin, 27 Aug, 2021.) – was followed soon after by a deal with Sandoz for its BAT1706 proposed bevacizumab biosimilar to Avastin. (Also see "[Bio-Thera Follows Hikma Deal With Sandoz Bevacizumab Alliance](#)" - Generics Bulletin, 8 Sep, 2021.)