

## IND-Enabling Studies and Chemical Synthesis Completed - Nine Months from Lead Selection

### SUMMARY

Client asked Ricerca to develop a robust chemical process, complete GLP toxicology to support a major program, and file an IND - all on a very aggressive timeline.

### APPROACH

Benchmarking, process development, and scale-up work were completed in parallel with an extensive salt screening program. This resulted in 1.6 kg non-GMP preparation for preliminary toxicology studies and bioanalytical development. Concurrently, analytical methods development and validation were completed in preparation for a subsequent 6 kg GMP API synthesis. API prepared by Ricerca, along with supporting CMC documentation and stability studies, were used throughout the GLP toxicology studies. The GMP material was used to support Phase I trials.

### RESULTS

From the start of the chemical development project to Phase I trial initiation total elapsed time was only nine months. From the client: "We did it in record time, on budget, and I very much appreciate that you did great science but also stayed committed to making the final deadline. We made a good decision to work with you. It has been a pleasure to work with such a talented team." (*VP of Drug Development*)

For detailed comments from the client, please contact Ricerca's Business Development Team at 440-357-3300.