

A Talent for Resolving Unusually Complex Issues

A customer came to us with a seven-year project to develop a novel human antibody from scratch, to treat multiple myeloma. There were no benchmarks, no relevant data on similar compounds because there were no similar compounds.

The first challenge: engage key opinion leaders

This project was never going to be easy or "by the book," so we put special care into enlisting key opinion leaders and consultants as primary investigators. Having the right specialists on our team enabled us to recruit subjects relatively quickly, despite extremely complex selection criteria and the rarity of the indication: relapsed/refractory multiple myeloma.

In addition, the compound was extremely difficult to store and administer. We made sure each site staff could get it letter perfect every time.

A quick trip up the learning curve

First we recruited six cohorts of patients to determine the maximum tolerated dose. Then we investigated the pros and cons of frequent dosages vs. only one dose per month.

But we expect the most exciting discoveries to come from tests combining the compound with standard treatments. In a preclinical murine model, the combination completely abolished bone lysis. Would it live up to its potential in humans?

Beyond getting it right: the importance of the relationship

Maintaining a close and cooperative customer relationship was critical to moving the study forward. The sponsor wanted effective and immediate responses to special requests, no dawdling, no discussions. They also wanted to work with a dedicated team that they already knew, right down to the same pharmacokinetic analysts. We delivered.

Preliminary results were so promising that a global biopharmaceutical company formed a strategic alliance with our customer specifically to advance this one compound.

ONCOLOGY



premier
research

Discovering Better Ways to Help Patients

Therapeutic Area:

Oncology

Indication:

Multiple myeloma

Study Compound:

Unique, fully human HuCAL antibody that targets the CD38 protein found on the surface of tumor cells in patients with multiple myeloma and certain leukemias

Scope of Study:

All services, from site management to data analysis. Phase I/IIa studies are under way, with Phase III to come. We are now in the third year of what we expect to be a seven-year project.

Patient Population:

Patients with relapsed/refractory multiple myeloma

Geographic Scope:

Eight sites staffed by oncology opinion leaders in Germany and Austria



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