



Modeling and Simulation Supports Competitive Product Profile Assessment

Modeling strategy provided sponsor timely and compelling support for positive efficacy signal of in-licensing candidate, helping to secure \$23 million financing round and advance compound to Phase IIb

Background

A specialty pharmaceutical company was seeking to provide rapid, quantitative support to fund its in-licensing strategy for an oral type 2 antidiabetic agent. Limited data from a single Phase IIa study was available on the drug candidate.

Challenge

As the sponsor worked to finalize its in-licensing strategy and secure deal terms, it became critical to provide investors with rapid yet rigorous early quantitative support for the potential of the compound's efficacy and safety profile versus currently marketed oral diabetes treatments, notably Avandia® (rosiglitazone) and Actos® (pioglitazone). In the absence of randomized controlled trials that directly compared the drug candidate's performance to that of established competitors, making an "apples to apples" assessment would be particularly challenging.

Solution

First, Certara developed models of the diabetes treatment landscape for key clinical endpoints (eg, FPG and HbA1c) using its in-house database of mean trial results from publicly available data sources. Public-source references extracted from the database for modeling included FDA Summary Basis of Approval (SBA) documents for Avandia and Actos, as well as relevant articles from the published scientific literature.

The literature-based disease models described the relationship of fasting blood glucose and HbA1c as a function of time, and also accounted for the differences in response due to factors such as disease baseline value, dose, patient characteristics, and run-in length of monotherapy trials. The models were then simulated to generate predictions of competitor trial arms that matched the exact characteristics of the available Phase IIa trial data for the drug candidate. Finally, the existing Phase IIa

Challenge

It was critical to provide investors with rapid yet rigorous early quantitative support for the potential of the compound's efficacy and safety profile.

Solution

Certara developed models of the diabetes treatment landscape for key clinical endpoints.

Benefit

The existing Phase IIa data from the drug candidate's short-term trial were compared with the matched, model-based simulations for Avandia and Actos to facilitate a robust evaluation of the NCE's early efficacy signal.

data from the drug candidate's short-term trial (eg, at 4 weeks) were compared with the matched, model-based simulations for Avandia and Actos to facilitate a robust evaluation of the NCE's early efficacy signal. A similar analysis was performed for key safety endpoints.

Benefit

The model-based meta-analysis established the NCE's parity with, and at higher doses superiority to, its competitors based on efficacy. This approach enabled the sponsor to simulate active control arms for the NCE that hadn't yet been run—in effect to conduct virtual “head to head trials” to demonstrate the compound's clinical and commercial potential.

Impact

The sponsor secured a \$23 million round of financing to successfully in-license the compound and initiated a Phase IIb trial.¹ The modeling and simulation strategy helped the sponsor provide rigorous and timely support of a positive efficacy and safety signal for the drug candidate versus competing treatments to support their in-licensing strategy and advance the compound with greater confidence into later-stage clinical development.²

References

1. Sponsor press releases and data on investigational program.
2. The literature-based models developed to support the in-licensing decision also offer the potential to be extended and combined with Phase IIb NCE data to support downstream trial design and program strategy decisions (eg, making predictions about steady-state HbA1c response to facilitate the design of pivotal trials).

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.