Puma's neratinib for HER2 positive tumors

Description: Puma Biotechnology's neratinib is an irreversible inhibitor of erbB1 (EGFR), HER2 and erbB4, in late-stage development for HER2 overexpressing breast cancer. Puma licensed neratinib from Pfizer in October 2011 (in the wake of the Wyeth acquisition). Pfizer was originally developing neratinib as adjuvant therapy and for first line treatment of metastatic HER2-overexpressing breast cancer. However, Puma has redirected neratinib's development to later lines of therapy as the most sensible and efficient path to market entry. This change in direction was in part conceding the dominant position that Roche holds in adjuvant and early line metastatic HER2-positive breast cancer with its three antibodies – Herceptin, Perjeta and Kadcyla.

Glaxo's Tykerb, a reversible small molecule HER2 inhibitor, is used for later line therapy and has a number of deficiencies that make it vulnerable to competitive threats like neratinib. In fact, neratinib's pivotal trial, conducted under SPA, is a head-to-head comparison between neratinib and Tykerb, both in combination with Xeloda in women who received two or more HER2-directed therapies in the metastatic breast cancer setting.

In this report, we review neratinib's clinical development program, its safety and tolerability profile, as well as the likelihood of phase III success and commercial opportunity across the various potential settings and indications.

Contents:
INTRODUCTION
- Breast cancer - Neratinib's lead indication
- HER2 and the ErbB family of receptors

Neratinib

EFFICACY PROFILE
- Comparison of neratinib and Tykerb monotherapy trials
- Xeloda combination trials
- Will Neratinib + Xeloda beat Tykerb + Xeloda?
- Early data in very late-line therapy with neratinib + temsirolimus is impressive
- Data in other potential indications should be available in 2013

SAFETY PROFILE
- The diarrhea associated with neratinib occurs mainly in early treatment
- Online open patient forum provide perspective on diarrhea's impact
- How does the safety of neratinib compare to that of Tykerb?
- Cardiotoxicity represents a theoretical clinical development risk

REGULATORY LANDSCAPE

COMPETITIVE LANDSCAPE
- Many HER2 targeted therapies are in development
- Boehringer's afatinib

THE MARKET AND REVENUE PROJECTIONS
- Late-line breast cancer therapy is an attractive entry point for neratinib
- Neratinib plus Torisel for end-stage disease
- The opportunity in breast cancer patients with brain metastases
- The neoadjuvant opportunity
- HER2 mutated lung cancer and breast cancer are niche opportunities

CONCLUSION
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