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London Wednesday July 6 2005 - Worth \$4.8 billion in 2004*, the cancer antihormonal therapies market is forecast to reach \$5.5 billion in value by 2014, with a compound annual growth rate (CAGR) of 0.9%. This low growth rate is due to the maturity and relative saturation of the market, as well as the increasing threat of key patent expiries and entry of generic competition. Despite the decline of some antihormonal therapy classes, opportunities for new growth within the market do exist. According to a new report from independent market analyst Datamonitor**, the aromatase inhibitor class will experience significant market growth, particularly in light of recent positive clinical trial data and America Society of Clinical Oncology (ASCO) recommendations that will serve to increase their profile and significantly increase uptake.

Antihormonal therapies are used to treat hormone-driven cancers, mainly breast cancer and prostate cancer, whose growth is fuelled by estrogen and testosterone respectively. Tamoxifen, the main product within the anti-estrogen drug class, currently forms the mainstay of antihormonal treatment of breast cancer. However, a shift in the breast cancer treatment paradigm is set to occur, away from tamoxifen towards the aromatase inhibitors, according to Datamonitor oncology analyst Fleur Pijpers.

“For about three decades, tamoxifen was the gold-standard antihormonal to treat breast cancer, with a standard regimen constituting five years of treatment. However results from several clinical trials have shown aromatase inhibitors to be superior to tamoxifen in efficacy, as well as having less toxicity.”

Comes highly recommended

Anti-estrogens block the effect of estrogen on breast cancer cells by binding to estrogen receptors. Aromatase inhibitors inhibit the action of the enzyme aromatase, which catalyzes the conversion of androstendione to estrone, a precursor of estrogen. By inhibiting aromatase, the production of estrogen is inhibited.

“As a result of these trials, in particular the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial, ASCO has recommended that the adjuvant treatment of postmenopausal hormone-receptor positive breast cancer patients should include an aromatase inhibitor as initial treatment or after treatment with tamoxifen,” she says.

“Because of ASCO’s recommendations, the aromatase inhibitors, worth \$1.1 billion in 2004, are set to realize peak sales of \$2.2 billion by 2010 before key patent expirations will result in a subsequent drop in sales to \$1.9 billion by 2014, which represents a CAGR of 4.0% over the period 2004-14. This increase is in line with the expected fall in anti-estrogen sales, decreasing in value from \$258m in 2004 to \$166m in 2014, at a CAGR of -3.7%.”

Datamonitor expects that an aromatase inhibitor, most likely AstraZeneca's Arimidex (anastrozole), will eventually replace tamoxifen as the gold-standard antihormonal therapy for breast cancer. However Novartis's Femara (letrozole) and Pfizer's Aromasin (exemestane) are also expected to enjoy increased uptake, Pijpers says. "This will become a more feasible prospect in coming years, as results from ongoing clinical trials comparing the various aromatase inhibitors with tamoxifen's current indications are made available. Although tamoxifen is expected to lose its gold-standard status, the drug is still expected to retain a sizable presence on the market for years to come."

In 2004, 50% of antihormonal therapy sales were attributed to the LHRH (luteinizing-hormone releasing hormone) analogs, 23% to the aromatase inhibitors, 20% to the anti-androgens, 5% to the anti-estrogens and 2% to other hormone antagonists- currently containing only one product: AstraZeneca's Faslodex (fulvestrant).

By 2014, these proportions are expected to change to 42% attributed to the LHRH analogs, 34% to the aromatase inhibitors, 18% to the anti-androgens, 3% to the anti-estrogens and 3% to Faslodex.

Treating prostate cancer

LHRH analogs & anti-androgens are used to treat prostate cancer. LHRH analogs initially stimulate the brain to release luteinising hormone, but with continued use cause down-regulation of the LHRH receptors in the brain, which reduces the amount of luteinising hormone and follicular stimulating hormone in the body. This in turn causes shutdown of testosterone production in the testes, resulting in chemical castration where testosterone levels drop by 95%, thereby reducing tumour growth. The initial stimulation of the brain to release luteinising hormone causes a testosterone 'flare', which is countered by administering an anti-androgen, which binds to testosterone receptors on prostate cancer cells and inhibit the tumour growth effects of testosterone.

In terms of volume, the LHRH analogs are set to decline at a CAGR of -1.5% between 2004 and 2014, while the anti-androgens will decline at a CAGR of -1.4%. This decrease in volume can be attributed primarily to key patent expiries and increasing generic competition, as well as a growth in chemotherapy use, which will lessen the role of the antihormonal therapies somewhat. As a result, opportunities for new growth in these classes of drugs are limited, Pijpers says.

"With the exception of aromatase inhibitors, all the remaining drug classes within the antihormonal therapies market will see a decline in sales growth, although volume is expected to remain more or less stable. The maturity of this market means further pipeline breakthroughs are unlikely unless significant clinical superiority is demonstrated," she says.

Ends

Notes for editors

*Seven major pharmaceutical markets: UK, France, Germany, Italy, Spain, US and Japan

** **Commercial Insight: Antihormonal Therapies – Aromatase Inhibitors Reinvigorate a Mature Market**

The antihormonal cancer therapy market is characterized by a mature nature and a relatively high level of saturation. Despite this, growth will continue slowly at a CAGR of 0.9% during 2004–14, with those areas in decline offset by clear potential from new products and line extensions. Datamonitor's report **Commercial Insight: Antihormonal Therapies – Aromatase Inhibitors Reinvigorate a Mature Market** reveals that generic competition continues to threaten, although effective lifecycle management can dilute the overall impact.

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