



Control of Selective Estrogen Receptor Modulators: Prevention of Hormonal-Dependant Breast Cancer

Use of a Progestinally Active Compound to Facilitate Broader and Safer use of SERMs for Breast Cancer Prevention

Intellectual Property ID Number

66

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Field

Breast Cancer Prevention

Technology

Use of a progestin (such as clomiphene) to ameliorate the side effects of a SERM (such as tamoxifen) used for breast cancer prevention.

Key Features

- Broadens the safe use of SERMs for prevention of breast cancer
- Some early validation provided by clinical studies

Stage of Development

Non-human primate and human clinical studies have been performed. The results of these studies are available under CDA.

Status

Seeking licensing partner

Patent Status

Issued U.S. Patent:
6,653,297

Selective Estrogen Receptor Modulators

Selective estrogen receptor modulators (SERMs) are used post-menopausally in hormone replacement therapy to prevent cardiovascular disease, osteoporosis, and breast cancer. SERMs have also been used pre-menopausally in contraception, and in the treatment of estrogen-sensitive conditions such as endometriosis, leiomyoma, dysfunctional uterine bleeding, premenstrual syndrome, and hormonal-dependent cancers of the breast, endometrium, and ovary. However, SERM-based treatments carry several undesirable side-effects, including proliferation of the endometrium, uterine bleeding and cyclotherapeutic withdrawal menstrual bleeding, gallbladder disease, hypertension, abnormal glucose tolerance, hypercoagulable states, and breast cancer. This invention centers on the use of progestins, such as clomiphene, to counter the side-effects of SERM-based drugs that are used for the prevention of breast cancer.

Use of Progestins to Broaden the Safe use of SERMs in Breast Cancer Prevention

The first and only SERM to be approved for breast cancer prevention is tamoxifen. The approval was specifically for use in prevention of breast cancer in women age 35 and older and characterized as being at high risk for getting breast cancer. This invention holds the promise of reducing the side effects in the currently treated population and enabling the safe treatment of populations that fall outside of the "high risk for breast cancer" definition by concomitant use of a progestin with a SERM.

The use of clomiphene to ameliorate the side-effects of a SERM was validated in non-human primate and human studies conducted by Dr. Hodgen and colleagues (un-published). In the non-human primate study, optimal dosing of clomiphene was achieved. This study was then carried over to humans in a study involving 50 women. Although optimal dosing was not found in this case, there was a trend towards attenuating SERM-related side-effects.

Market

The target market for a breast cancer chemopreventive drug includes women that fall within a high risk group. It is estimated that there are approximately 8.5 million women who are at high risk for breast cancer in the United States alone.

To date, only tamoxifen (Nolvadex) has approved by the FDA to help protect high-risk women from getting breast cancer. Other drugs that are being looked at for this indication include another SERM called raloxifene (Evista), aromatase inhibitors, and nonsteroidal anti-inflammatory drugs.

Total worldwide sales for tamoxifen (both generic and branded) were approximately \$1.8 billion in 2003 and distributed mostly between AstraZeneca, Barr Laboratories, and Schering AG (under the name Jenoxifen) and Teva. It is unclear what portion of these sales is attributable to the prophylactic treatment of breast cancer.

Opportunity

EVMS is seeking licensing partners to commercialize this technology.