

Prioritising patients over profits

Australia's first 'for-benefit' pharmaceutical company directing 100 per cent of profits to patient support & medical research

Today's launch of the nation's first 'for-benefit' pharmaceutical company will see 100 per cent of profits injected into local breast cancer patient support and medical research organisations.

For Benefit Medicines' (FBM) – an innovative social enterprise set to challenge the conventional for-profit pharmaceutical model – will distribute ALL profits from the sale of its two aromatase inhibitor medications, Anastrozole FBM (anastrozole) and Letrozole FBM (letrozole), to Breast Cancer Network Australia (BCNA) and Breast Cancer Institute of Australia (BCIA). The FBM medications are now available on prescription, and for dispensing through pharmacies nation-wide.

According to Professor Bruce Mann, Director of the Breast Service at Royal Melbourne and Royal Women's Hospitals, and Board member of BCNA and BCIA, the concept of a for-benefit pharmaceutical company is way overdue, and an initiative from which patients stand to significantly benefit.

"FBM is pioneering a new era of social enterprise in pharmaceutical healthcare in which companies will operate exclusively for social causes, patient benefit and medical innovation.

"FBM represents the perfect hybrid of a formally structured commercial entity that distributes products that improve quality of life, while directing profits to beat diseases," said Prof Mann.

"By choosing an FBM product, the medical community will be investing in local patient support programs today, and facilitating medical research to improve treatments tomorrow."

With annual sales of aromatase inhibitors in Australia exceeding \$20 million¹ and the generic segment of the drug class comprising approximately 50 per cent of market share,¹ FBM plans to capture and inject millions of dollars into patient support and medical research for the nation's third most commonly diagnosed cancer.²

Breast Cancer Network Australia (BCNA) CEO, Christine Nolan, whose organisation comprises more than 100,000 members, 90 per cent of whom are women diagnosed with breast cancer, has welcomed the philanthropic initiative, and its shared goals of providing breast cancer patient support, information, treatment and care.

"FBM's model is driven by compassion and places people before profits.

"An estimated 15,600 women will be diagnosed with breast cancer in Australia this year,² while the projected number of deaths from the disease will exceed 3,000,²" Ms Nolan said.

"While fundraising constitutes the mainstay of our revenue, having an initiative that provides a constant, daily stream of financial support, is both remarkable and warmly embraced.

"A simple change in prescription will help ensure that no Australian has to face breast cancer alone," said Ms Nolan.

The Breast Cancer Institute of Australia (BCIA) is the fundraising department of the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) – the largest, independent, oncology clinical trials research group in Australia and New Zealand committed to the treatment, prevention and cure of breast cancer.

ANZBCTG CEO, Dr Soozy Smith, says clinical trials have played a significant role in improving breast cancer treatments and the fall in breast cancer mortality rates, particularly over the past 20 years.

"Funding is vital to ensure our researchers can pursue the answers to important scientific questions and improve outcomes for people at risk, or diagnosed with breast cancer.

"This [FBM] initiative is a unique business model which puts the focus on improved health outcomes in the community, by making breast cancer research and support a priority," Dr Smith said.

"Funding for breast cancer clinical trials will help our researchers find new and improved treatment and prevention strategies, and ultimately save more lives."

Despite attending annual routine mammograms for years, mother-to-three adult children now approaching retirement, Kate, Melbourne, missed one scheduled appointment, and a year later, was diagnosed with early stage breast cancer. After undergoing two surgeries, six cycles of chemotherapy, and radiotherapy, Kate was placed on a five year course of letrozole.

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Kate describes the FBM model as “exciting”, citing “for someone who has experienced breast cancer, like myself, I like the idea that a woman can ask her doctor or pharmacist for an FBM medication, knowing that all of the profits are being directed into programs that are helping other women living with breast cancer now, and future research.”

All FBM medications are approved by the Australian Government’s Therapeutic Goods Administration (TGA) for use in Australia, and are required to meet the same strict regulations applied to the original brand, with regard to quality, safety and effectiveness.

Anastrozole FBM and Letrozole FBM are indicated for adjuvant (optimally supportive) treatment of early breast cancer^{3,4} and treatment of advanced breast cancer in postmenopausal women with oestrogen/progestogen receptor positive disease.^{3,4}

According to Professor John Boyages, Professor of Breast Oncology, Macquarie University, Sydney, and author of *Breast Cancer: Taking Control*, “at least two-thirds of female breast cancers are hormone receptor positive, meaning the body’s natural oestrogen can encourage them to grow and reproduce⁵ – a bit like putting fertiliser on a weed.

“Although breast cancer can occur in younger women, the majority of breast cancers are diagnosed in women who have gone through the menopause,”^{6,7} Prof Boyages said.

“Aromatase inhibitors are often used in these post-menopausal women with hormone receptor positive breast cancer after surgery, chemotherapy or radiotherapy, by stopping the production of small amounts of oestrogen that is produced after the menopause and thereby preventing recurrence of their disease.”⁵

The brainchild of social entrepreneurs, Barry Frost, John Hurley, Mark Davies Karvonen and Jackson Su, who share more than 80 years’ combined experience in healthcare and management, FBM is the first enterprise of its kind in Australia, if not worldwide.

“The concept of a for-benefit pharmaceutical organisation stems from the idea that once a brand goes off patent, it is then possible to have products from which all profits generated may be reinvested into the community,” said FBM Director, Dr Barry Frost, PhD.

“Choosing an FBM generic that serves the same treatment purpose, will ensure profits go directly to patient support and breast cancer research.”

“Our ultimate goal is to help improve the lives of our fellow Australians. The FBM initiative provides an opportunity for doctors, nurses, pharmacists and breast cancer patients to raise millions of dollars for BCNA and BCIA each year. However, for this to become a reality, we need all of these parties to get behind the cause and support FBM,” said Dr Barry Frost.

Anastrozole FBM and Letrozole FBM are available on the Pharmaceutical Benefits Scheme (PBS) at the same cost to patients as their current aromatase inhibitor treatment.

“By choosing an FBM product, patients living with breast cancer will be investing in local breast cancer support programs today, and breast cancer medical research for tomorrow,” John Hurley said.

“All these patients need to do, is to ask their doctor and pharmacist for the FBM product, which will incur no extra cost.”

FBM believes **every cloud has a silver lining**, meaning that patients can help others with the same condition by using an FBM product. As such, cloud imagery features prominently on all FBM product packaging for ease of identification.

FBM plans to expand its range of generic therapies, and areas of giving, in order to distribute further profits from medication sales to additional patient support and medical research organisations in corresponding therapeutic fields. FBM’s pipeline for this year up until 2020 comprises treatments for prostate cancer, Alzheimer’s, depression, schizophrenia and multiple sclerosis.

FBM is restricted by its Constitution from any distribution of returns to shareholders. Rigid transparency protocols, independent auditing and a low cost base underpin its for-benefit charter.

To learn more about FBM, head to www.forbenefitmedicines.com.au or call 1300 656 256.

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FULL MEDIA KIT: Available for download WED, NOV 25, 2015 from www.forbenefitmedicines.org

BROADCAST VISION: Available via satellite feed @ 9:15am ADST on WED, NOV 25, 2015 from 7 Network (SYD) – please record & ask Ch 7 in your capital city to on-pass, if an affiliate

Anastrozole FBM (anastrozole) Product Information

PBS Information: Restricted benefit.

Breast cancer. **Clinical criteria:** The condition must be hormone receptor positive.
Refer to PBS Schedule for full Restricted benefit information.

See Approved Product Information before prescribing.

Approved Product Information available on request

Indications: Adjuvant treatment of early breast cancer in postmenopausal women with oestrogen/progestogen receptor positive disease (see "Clinical Trials"). First line treatment of advanced breast cancer in postmenopausal women with oestrogen/progestogen receptor positive disease. Treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy. Patients with oestrogen receptor negative disease and patients who have not responded to previous tamoxifen therapy rarely respond to anastrozole. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients; pregnancy, lactation. **Precautions:** Patients with creatinine clearance < 30 mL/min; severe hepatic impairment. Driving and using machinery. Consider adequate contraception in women who have the potential to become pregnant, including women who are perimenopausal or who recently became postmenopausal, until postmenopausal status is fully established. Monitoring of bone health. **Adverse Reactions:** • Most common adverse reactions: hot flushes, nausea, asthenia, joint pain/stiffness, headache, rash. • Common adverse reactions are: anorexia, vomiting, diarrhoea, alopecia, bone fractures, hypercholesterolaemia, somnolence, Carpal Tunnel Syndrome, vaginal dryness, vaginal bleeding; increases in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase. • Uncommon, rare or very rare adverse reactions and potentially serious: trigger finger, urticaria, increases in gamma-GT and bilirubin, hepatitis, ischemic cardiovascular disease, erythema multiforme, anaphylactoid reaction, Stevens-Johnson syndrome, angioedema. **Dosage and Administration:** 1 mg once daily. No dose adjustment needed for elderly patients or patients with mild renal impairment (creatinine clearance ≥ 30 mL/min) or mild hepatic impairment. For early breast cancer, the recommended total duration of hormonal therapy is five years. For patients being switched to anastrozole from tamoxifen, the switch should occur after completion of two to three years of tamoxifen therapy. **Presentation:** 1mg tablets; packs of 30. **Sponsor:** Southern Cross Pharma Pty Ltd, (ABN 47 094 447 677), 56 Illabunda Drive, Malua Bay NSW, 2536. **Supplier:** For Benefit Medicines Pty Ltd, (ABN 56 155 126 346), 27 Kirrawee Rd, North Gosford, NSW, 2250. (ANAFBM14012014.doc). Item No: FBM025. November 2015.

Letrozole FBM (letrozole) Product Information

PBS Information: Restricted benefit.

Breast cancer. **Clinical criteria:** The condition must be hormone receptor positive.
Refer to PBS Schedule for full Restricted benefit information.

See Approved Product Information before prescribing.

Approved Product Information available on request

Indications: For the treatment of postmenopausal women with hormone receptor positive breast cancer (see "Clinical Trials"). The safety and efficacy of neoadjuvant use of letrozole has not been established. Letrozole is not indicated in hormone receptor negative disease. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients; premenopausal endocrine status; pregnancy, lactation. **Precautions:** Patients with creatinine clearance < 30 mL/min; severe hepatic impairment; concomitant use of drugs that are mainly metabolised by cytochrome P450 2A6 or 2C19 isoenzymes and whose therapeutic index is narrow. Driving and using machinery. Consider adequate contraception in women who have the potential to become pregnant, including women who are perimenopausal or who recently became postmenopausal, until postmenopausal status is fully established. Monitoring of bone health. **Adverse Reactions:** • Most common adverse reactions: hot flushes, nausea, fatigue, arthralgia. • Common adverse reactions are: anorexia, appetite increase, peripheral oedema, headache, dizziness, malaise, vomiting, dyspepsia, constipation, diarrhoea, alopecia, increased sweating, rash, myalgia, bone pain, arthritis, osteoporosis, bone fractures, weight increase, hypercholesterolemia, depression. • Uncommon, rare or very rare adverse reactions and potentially serious: leukopenia, cataract, cerebrovascular accident or infarction, thrombophlebitis, pulmonary embolism, arterial thrombosis, general oedema, ischemic cardiovascular disease, angioedema, anaphylactic reaction, hepatitis, toxic epidermal necrolysis, erythema multiforme. **Dosage and Administration:** 2.5 mg once daily. No dose adjustment needed for elderly patients or patients with mild renal impairment (creatinine clearance ≥ 30 mL/min). Treatment should continue until tumour progression is evident. **Presentation:** 2.5mg tablets; packs of 30. **Sponsor:** Southern Cross Pharma Pty Ltd, (ABN 47 094 447 677), 56 Illabunda Drive, Malua Bay NSW, 2536. **Supplier:** For Benefit Medicines Pty Ltd, (ABN 56 155 126 346), 27 Kirrawee Rd, North Gosford, NSW, 2250. (LETFBM03022014.doc). Item No: FBM0024. November 2015.

For Benefit Medicines Pty Ltd, ABN 56 155 126 346, 27 Kirrawee Rd, North Gosford, 2250. Ph. 1300 656 256, Fax (02) 9457 1031. www.forbenefitmedicines.com.au. FBM017. November 2015.

This release is intended for healthcare professionals only.

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